UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHANNON MAHONEY, individually and on behalf of herself and all others similarly situated,

Plaintiff,

v.

ENDO HEALTH SOLUTIONS, INC., a Delaware corporation; ENDO PHARMACEUTICALS, INC., a Delaware corporation; GENERICS INTERNATIONAL (US PARENT), INC., a Delaware corporation d/b/a Qualitest Pharmaceuticals; GENERICS INTERNATIONAL (US), INC., a Delaware corporation; GENERICS BIDCO I, LLC, a Delaware limited liability company; GENERICS BIDCO II, LLC, a Delaware limited liability company; GENERICS INTERNATIONAL (US HOLDCO), INC., a Delaware corporation; GENERICS INTERNATIONAL (US MIDCO), INC., a Delaware corporation; and VINTAGE PHARMACEUTICALS, LLC, a Delaware limited liability company,

Defendants.
_____/

CASE NO. 15 Civ. 9841

CLASS ACTION

JURY TRIAL DEMANDED

FIRST AMENDED CLASS ACTION COMPLAINT

Plaintiff Shannon Mahoney ("Plaintiff" or "Mahoney"), on behalf of herself and all others similarly situated, files this Complaint against Defendants Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Generics International (US Parent), Inc.; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Holdco), Inc.; Generics International (US Midco), Inc.; and Vintage Pharmaceuticals, LLC (collectively "Defendants"), and alleges as follows:

INTRODUCTION

1. This is a class action lawsuit filed on behalf of individuals and entities who paid for Qualitest Multi-Vitamin with Fluoride Chewable Tablets ("Chewable Tablets"), which are available only by prescription and are goods sold for human consumption. Unlike children's multivitamins available over the counter throughout the United States, Qualitest-branded Chewable Tablets are marketed and sold for a specific purpose – delivery of a fixed dose of fluoride for those children whose dentists or physicians have determined that supplemental fluoride is necessary for cavity prevention.

2. Defendants marketed and sold the Chewable Tablets purporting to contain fluoride in three different concentrations – 1 milligram, 0.5 milligrams, and 0.25 milligrams of fluoride per tablet. The concentration is specified by the prescribing practitioner in a prescription, and the specific concentration dispensed is clearly disclosed on the product label. The Plaintiff, consumers, dentists, physicians, and pharmacists all rely on these labels to determine the fluoride dosage amount in the Chewable Tablets.

3. From some point in 2007 through July 2013, however, the Qualitest Chewable Tablets Defendants manufactured consistently contained less than 50% of the amount of fluoride claimed on their labels. Defendants misrepresented the true dosage of the Qualitest products for years and deceived millions of parents, dentists, pediatricians, insurers, and others about the amount of fluoride being delivered to children taking the Chewable Tablets.

4. Based on the current state of scientific research, delivery of a sub-therapeutic dose of fluoride has the same effect as a placebo.

PARTIES, JURISDICTION, AND VENUE

5. Plaintiff is, and at all material times was, a resident and citizen of Orange County, New York. Plaintiff purchased Chewable Tablets during the class period from pharmacies in New York for her minor children, B.M. and R.M.

6. Defendant **Endo Health Solutions, Inc.**, ("Endo Health") formerly known as Endo Pharmaceuticals Holdings, Inc., is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health describes itself as a "specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services." The Qualitest brand is one of Endo Health's four business "segments."

7. Defendant **Endo Pharmaceuticals, Inc.** ("Endo") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo purchased the Qualitest brand from a subsidiary of Apax Partners, L.P., in 2010.

8. Defendant **Generics International (US Parent), Inc.** ("GIUSP") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. GIUSP is a direct subsidiary of Endo. According to Endo Health filings with the Securities and Exchange Commission, GIUSP does business as "Qualitest Pharmaceuticals." Endo purchased GIUSP from a subsidiary of Apax Partners, L.P., in 2010.

9. Defendant **Generics International (US), Inc.** ("GIUS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. According to the Alabama Secretary of State, GIUS had its principal office at 130 Vintage Drive in Huntsville, Alabama, until February 2013. GIUS is indirectly owned by GIUSP.

10. Defendants **Generics Bidco I, LLC** and **Generics Bidco II, LLC** (together, "Generics Bidco") are Delaware limited liability companies that, upon information and belief,

have their principal place of business in Malvern, Pennsylvania.

11. Defendants **Generics International (US Holdco), Inc.** ("Generics Holdco") and **Generics International (US Midco), Inc.** ("Generics Midco") are Delaware corporations that, upon information and belief, have their principal places of business in Malvern, Pennsylvania.

12. Defendant **Vintage Pharmaceuticals, LLC** ("VPLLC") is a Delaware limited liability company with its principal place of business at 130 Vintage Drive in Huntsville, Alabama. VPLLC currently manufactures all generic drugs labeled with the Qualitest brand, including the Chewable Tablets that give rise to the claims in this Complaint.

13. This Court has jurisdiction under 28 U.S.C. § 1332(d)(2)(A) because this is an action for a sum exceeding $5,000,000, exclusive of interest and costs, and Plaintiff is a citizen of New York, and at least one Defendant is a citizen of a state other than New York.

14. This Court has personal jurisdiction over each of the Defendants. Defendants supplied the deficient Chewable Tablets to consumers in New York and received payment for those Chewable Tablets from individuals and entities in New York. As such, Defendants have purposely availed themselves of the privilege of conducting business in New York and are subject to the jurisdiction of New York courts. N.Y. C.P.L.R. § 302(a)(1). Moreover, certain Defendants, including Endo and GIUS, who have authority to act on behalf of the remaining Defendants, are registered to do business in New York, which is a constructive consent to personal jurisdiction.

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because Plaintiff's causes of action accrued within this judicial district and a substantial part of the events and omissions giving rise to the Plaintiff's claims occurred here. Plaintiff is a resident of Montgomery, Orange County, New York, and purchased the defective Chewable Tablets at a

pharmacy in this District.

FACTUAL ALLEGATIONS

ADA Recommendations on Fluoride

16. It is now universally accepted that fluoride helps prevent "dental caries," more commonly known as tooth decay. Dental caries is an infectious, transmissible disease in which bacterial by-products (*i.e.*, acids) dissolve the mineralized surfaces of teeth. Unchecked, the bacteria can penetrate the dissolved tooth surface, attack the underlying dentin, and reach pulpal tissues. Dental caries can result in loss of tooth structure, pain, and tooth loss and can progress to acute systemic infection. The Centers for Disease Control and Prevention (the "CDC") reported that from 1999 through 2004, 42% of U.S. children ages 2 to 11 years experienced dental caries in their primary teeth and 59% of U.S. adolescents ages 12 to 19 years experienced dental caries in their permanent teeth.

17. The American Dental Association ("ADA") and the American Academy of Pediatrics ("AAP") both advocate that all cities, towns, and other municipalities "fluoridate" their community drinking water. This process involves adding fluoride to drinking water, thus assuring that people, particularly children, receive daily fluoride dosages in their diet. According to the CDC, in 2010, 69% of the United States population received optimally fluoridated community drinking water while 31%, or approximately 95,480,000 people, did not receive fluoride through community water sources.

18. For communities that do not have fluoridated water, the ADA and the AAP recommend those children up to age 16 receive daily dietary fluoride supplements in order to prevent cavities and tooth decay. These dietary fluoride supplements can take the form of topical applications, liquid drops, chewable fluoride tablets, or chewable multivitamins with fluoride.

19. Since 1958, the ADA and the AAP have been publishing recommended dietary fluoride supplemental dosage schedules for children. The following recommendations were adopted in 1994 and restated in 2010. The recommendation includes a sliding scale to account for a child's age and the amount of fluoride in the drinking water of the community where the child lives:

Dietary fluoride supplement schedule

	Fluoride ion level in drinking water (ppm)*		
Age	Less than 0.3ppm	0.3-0.6ppm	Greater than 0.6 ppm
Birth-6 months	None	None	None
6 months-3 years	0.25 mg/day**	None	None
3-6 years	0.50 mg/day	0.25 mg/day	None
6-16 years	1.0 mg/day	0.50 mg/day	None

*0.1 part per million (ppm) = 1 milligram/liter (mg/L)
**2.2 mg sodium fluoride contains 1 mg fluoride ion

These recommendations are hereinafter referred to as the "ADA-AAP Guidelines." Dentists and physicians throughout the United States rely upon this chart in prescribing fluoride supplements to children.

The Distinction Between "Fluoride" and "Sodium Fluoride"

20. The information marked with a double asterisk "**" in the ADA-AAP Guidelines chart clarifies the nature of the fluoride recommendation. Dental fluoride can be obtained from different sources, most commonly "sodium fluoride" and "stannous fluoride." Sodium fluoride is a specific salt form of fluoride. "Sodium fluoride" is not the same as "fluoride." Sodium Fluoride (NaF) disassociates into 54.5% sodium (Na^+) and 45.5% fluoride ion (F^-). The fluoride ion accounts for 45.5% of the sodium fluoride by weight.

21. As noted in the ADA chart, it takes 2.2 milligrams of sodium fluoride to yield 1 milligram of fluoride. Thus, the official ADA and AAP recommendation – and the one relied

upon by dentists and pediatricians – calls for prescribing dosages of fluoride ion, not dosages of sodium fluoride.

The Market for Chewable Fluoride Vitamins

22. To satisfy the ADA-AAP Guidelines, many companies manufacture and sell products marketed as chewable "Multivitamins with Fluoride." As of 2013, at least fifteen (15) companies were in the business of selling chewable "Multivitamins with Fluoride" in the United States. Universally, these companies manufacture and sell their "Multivitamins with Fluoride" products in only three fluoride dosage sizes – 0.25 mg, 0.5 mg and 1 mg of fluoride. These dosage amounts correspond to the ADA-AAP Guidelines' dosage recommendations. Thus, a child 3-6 years old, who lives in a community with less than 0.3 parts per million of fluoride in community drinking water (or obtained through other daily sources), should be prescribed a daily 0.5 mg fluoride supplement tablet. A child 6-16 years old, who lives in same community, should be prescribed a daily 1.0 mg fluoride supplement tablet.

23. These fluoride products are not sold "over the counter." They must be prescribed by a licensed dentist or physician in order to be purchased. At the same time, however, these products are not approved by the FDA. Sodium fluoride chewable tablets are registered in the FDA National Drug Code Registry as "unapproved drug other." Accordingly, neither the product nor the labeling needs to be approved by the FDA.

24. Consumers, physicians, dentists, providers of health insurance and pharmacy benefits, and pharmacists dispensing chewable fluoride vitamins rely on the labels and representations made by the manufacturers, like the Defendants, of these products. For example, when a physician writes a prescription for a multivitamin with 0.5 mg of fluoride, the physician is relying on the manufacturer of the multivitamin to correctly state the amount of fluoride in that

multivitamin so the patient receives the correct dosage amount. Similarly, when filling those prescriptions, pharmacists rely on the representations made by the manufacturer of the multivitamins with fluoride about the amount of fluoride contained in the multivitamins. When a pharmacist fills a prescription for multivitamins with 0.5 mg of fluoride, the pharmacist relies on the manufacturers' labels that state the amount of fluoride contained in the multivitamins in order to ensure the consumer is receiving the correct dosage amount of fluoride based on the prescription. Likewise, consumers too rely on manufacturers' labels to make sure that they are receiving the correct amount of fluoride in the amount prescribed by the physician and filled by the pharmacist. Consumers, physicians, and pharmacists rely on the drug manufacturer to correctly state the fluoride dosage amounts, because as the manufacturer of the drug, they are the one who sets the fluoride dosage amount through the manufacturing process.

25. Defendants possess unique and specialized expertise with regard to the manufacture of pharmaceuticals including the Chewable Tablets, and with respect to their fluoride content, as to which Defendants were uniquely situated to evaluate because they alone knew the master formula by which the Chewable Tablets were produced. Defendants also had a special relationship with Plaintiff and the Class Members by virtue of the fact that the Chewable Tablets were dispensed by prescription only in a context that, unlike the sale of other products, is designed to provide a high level of assurance that what is being dispensed is in fact what it purports to be, a fact of which Defendants, as companies permitted to manufacture and sell pharmaceuticals in the United States, were well aware. Defendants' false representations regarding the fluoride content of the Chewable Tablets were made repeatedly during the Class Period, including every time Plaintiff or a Class Member received and paid for a prescription of the Chewable Tablets.

26. Defendants also knew that the Chewable Tablets were destined to be consumed by children and that Plaintiff and the Class Members would use the Chewable Tablets for the particular purpose of providing supplemental fluoride to children. Defendants, by making representations to, among others, Plaintiff and the Class Members, pharmacists, formularies such as Golden Rule, and the United States Food and Drug Administration, intended to cause Plaintiff and the Class to rely on Defendants' representations about the fluoride content of the Chewable Tablets. Through the distribution of these representations through channels that Defendants knew would be trusted by Plaintiff and Class Members, Defendants established a special relationship with them that in turn established a duty to give correct information.

27. Health insurance companies and providers also pay for the Chewable Tablets for their insureds. In so doing, they rely on the representations made by Defendants about the fluoride content of the Chewable Tablets in undertaking to add the Chewable Tablets to the list of approved prescription drugs for which they will pay on behalf of their insureds. Those representations, which include product labeling, are made to, among others, formularies such as Golden Rule and the United States Food and Drug Administration. Defendants, as part of the pharmaceutical industry, know this and provide the fluoride content information to these sources with the expectation that health insurance companies and providers will rely on this information in adding the Chewable Tablets to their list of approved prescriptions and in paying for the Chewable Tablets. Defendants' false representations regarding the fluoride content of the Chewable Tablets were made in this manner repeatedly during the Class Period.

28. The Chewable Tablets are sold as generic products. That is, prescribers do not specify a brand when prescribing chewable multivitamins with fluoride, but instead they are sold and dispensed based on their fluoride content without regard to manufacturer.

Defendants' Labeling Claims

29. Defendants, through one or more of their subsidiaries, were for many years the dominant manufacturer and distributor of "Multivitamins with Fluoride" in the United States, accounting in some years for about one-half of all such products sold. Defendants manufactured and distributed Chewable Tablets under the "Qualitest Pharmaceuticals" brand in all three dosage sizes – 0.25 mg, 0.5 mg, and 1 mg – and in numerous flavors. Among others, Defendants used the following National Drug Codes: 00603-4381-21, 00603-4382-21, 00603-4383-21, 00603-4713-21, 00603-4714-21, and 00603-4715-21.

30. Upon information and belief, Defendants also produced Qualitest-branded Chewable Tablets for repackaging and relabeling by other companies, including Physicians Total Care, Inc. ("PTC").

31. Defendants' labeling for these products consisted of two parts, an outside label affixed to the bottle and a package insert. Plaintiff has attached as **Composite Exhibit A** sample outside labels for each dosage size of Qualitest-branded Chewable Tablets. Plaintiff has attached as **Exhibit B** a sample package insert, the relevant language of which is the same for every package of Qualitest-branded Chewable Tablets, regardless of dosage size. **Exhibit C** is a sample outside label for PTC-branded Chewable Tablets, which makes substantially the same representations as found on the Qualitest-branded Chewable Tablet labels.

32. In bold letters, the outside of each label states the alleged dosage of fluoride. As an example, the outside labels attached as Exhibit A and Exhibit C identify the title of the product as follows:

"MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE 1 mg."

See Exhibits A & C. The "Nutrition Facts" component of the outside label repeats these claims:

"FLUORIDE . . . . . 1 mg"

Id.

33. The outside labels for both Qualitest-branded and PTC-branded Chewable Tablets state unequivocally, in two places, that the tablets contain 1 milligram of "fluoride." The pattern repeats itself for each dosage size as well. *See Id.*

34. The package inserts for Qualitest-branded Chewable Tablets repeat the fluoride claim in a section titled "INDICATIONS AND USAGE." That section follows the ADA and AAP guidelines precisely in terms of the dosage schedule for fluoride. It provides:

> Supplementation of the diet with fluoride for caries prophylaxis.
>
> Multivitamin with 1 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.
>
> Multivitamin with 0.5 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.
>
> Multivitamin with 0.25 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.
>
> Multivitamin with Fluoride Chewable Tablets supply significant amounts of Vitamins A, C, D, E thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop.
>
> Thus, in a single easy-to-use preparation, children obtain ten essential vitamins and the important mineral, fluoride.
>
> The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

See Exhibit B. Upon information and belief, PTC-branded tablets contained package inserts with

nearly identical information. Based on this insert, Defendants knew and expected that dentists and physicians would prescribe and dispense Chewable Tablets to children to prevent tooth decay, *i.e.*, for caries prophylaxis.

35. As indicated above, the package insert even cites to the ADA-AAP Guidelines and recommends that, for example, the "1 mg" tablet be prescribed to children between 6 and 16 years old who live in areas with less than 0.3 ppm fluoride in the drinking water. This leaves no doubt that the Qualitest-branded Chewable Tablet purported to deliver 1 milligram of fluoride ion. In reality, as set forth below, the Qualitest-branded Chewable Tablets delivered, on average, less than half that amount. Upon information and belief, the PTC-branded tablets will reveal the same result.

Defendants Admit Qualitest Products Do Not Contain the Claimed Amount of Fluoride

36. On or about December 16, 2015, the Court entered the Stipulation and Order of Settlement and Dismissal in *United States of America v. Vintage Pharmaceuticals, LLC, d/b/a Qualitest Pharmaceuticals, et al.*, No. 13-Civ-1506 (DLC) (S.D.N.Y.) [D.E. 17] (the "Stipulation"). The Defendants here are all named in and signatories to the Stipulation.

37. The misconduct set forth herein is also set forth in the Complaint-in-Intervention of the United States, filed against Defendants on December 16, 2015 in *United States of America v. Vintage Pharmaceuticals, LLC, d/b/a Qualitest Pharmaceuticals, et al.*, No. 13-Civ-1506 (DLC) (S.D.N.Y.) [D.E. 15]. The underlying *qui tam* lawsuit that preceded the Complaint-in-Intervention and the Stipulation was, according to the docket in that case, filed on March 6, 2013. In its annual report for the year ending December 31, 2015, filed with the United States Securities and Exchange Commission and dated February 29, 2016, Endo International PLC, the corporate parent of Defendants, admitted that "[i]n April 2013, our subsidiaries [Endo

Pharmaceuticals, Inc.] and Qualitest, received CIDs from the U.S. Attorney's Office for the Southern District of New York. The CIDs request documents and information regarding the manufacture and sale of chewable fluoride tablets and other products sold by Qualitest." The annual report notes that a resolution was reached regarding the claims arising therefrom.

38. As a result of these documents and other filings, including the instant lawsuit, and their own knowledge of the "master formula" and its inconsistency with the product label and insert, which they concealed from the public until the Stipulation was filed, Defendants were on notice about the deficiencies and misconduct alleged herein, the harm they caused to Plaintiff and the Class, and Plaintiff's and the Class' claims, yet took no steps to remedy that harm or to alert Plaintiff and the Class about the deficiencies in the Chewable Tablets. Moreover, Defendants were aware as early as April 2013 that the government had discovered their misconduct, but still took no steps to remedy that harm or to alert Plaintiff and the Class about the deficiencies in the Chewable Tablets. In fact, to this day, Defendants have taken no steps to alert the patients who took the Chewable Tablets that they contain less fluoride than their product labels and inserts represent.

39. As disclosed in Exhibit C attached to the Complaint-in-Intervention, the Chewable Tablets were manufactured in "batches" of up to three million tablets at a facility in Huntsville, Alabama. To manufacture each batch, Defendants created a "manufacturing batch record" that contained a "master formula" specifying the amount of each ingredient used. During the relevant period, Defendants relied on the same three master formulas to manufacture the 1 mg, 0.5 mg, and 0.25 mg Chewable Tablets.

40. In the Stipulation, Defendants admitted, acknowledged, and accepted responsibility for the fact that they used sodium fluoride (chemically, 2.2 mg of sodium fluoride

contains 1 mg of fluoride ion) as an ingredient to manufacture the Chewable Tablets. Defendants also admitted that instead of using 2.2 mg of sodium fluoride as an ingredient to secure 1 mg of fluoride ion for the 1 mg Chewable Tablet, Defendants used only 1 mg of sodium fluoride. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg tablet and 0.55 mg of sodium fluoride for the 0.25 mg tablet, Defendants used 0.5 mg of sodium fluoride and 0.25 of sodium fluoride, respectively.

41. In other words, a "1 mg" Qualitest-branded Chewable Tablet did not contain 1 milligram of fluoride as claimed. It contained approximately 45% of the alleged dosage of fluoride. The same is true of the lower dosage tablets: the 0.5 mg and 0.25 mg Chewable Tablets both contained, on average, approximately 45% of the claimed dosage of fluoride.

42. In the Stipulation, Defendants admitted, acknowledged, and accepted responsibility for the fact that the Qualitest Chewable Tablets did not contain 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion, respectively. The 1.0 mg Qualitest Chewable Tablet contained approximately 0.44 mg of fluoride ion; the 0.5 mg Qualitest Chewable Tablet contained approximately 0.22 mg of fluoride ion; and the 0.25 mg Qualitest Fluoride Tablet contained approximately 0.11 mg of fluoride ion.

43. This sub-potency issue was not isolated to particular bottles, lot numbers, NDC numbers, flavors, dosages, or shipments. Instead, the defect pervaded *all* Chewable Tablets "batches" manufactured by Defendants from 2007 through the middle of 2013.

44. Defendants possess unique and specialized expertise with regard to the manufacture of pharmaceuticals including the Chewable Tablets, and with respect to their fluoride content, as to which Defendants were uniquely situated to evaluate because they alone knew the master formula by which the Chewable Tablets were produced. Defendants also had a

special relationship with Plaintiff and the Class Members by virtue of the fact that the Chewable Tablets were dispensed by prescription only in a context that, unlike the sale of other products, is designed to provide a high level of assurance that what is being dispensed is in fact what it purports to be, a fact of which Defendants, as companies permitted to manufacture and sell pharmaceuticals in the United States, were well aware.

45. Defendants also knew that the Chewable Tablets were destined to be consumed by children and that Plaintiff and the Class Members would use the Chewable Tablets for the particular purpose of providing supplemental fluoride to their children. Defendants, by representations to, among others, Plaintiff and the Class Members, physicians, pharmacists, formularies such as Golden Rule, and the United States Food and Drug Administration, intended to cause Plaintiff and the Class to rely on Defendants' representations about the fluoride content of the Chewable Tablets, and were aware and contemplated that they would do so. Through the distribution of these representations through channels that Defendants knew would be trusted by Plaintiff and Class Members, Defendants established a special relationship with them that in turn established a duty to give correct information.

46. Because of their specialized expertise in manufacturing pharmaceuticals including the Chewable Tablets, their unique knowledge of the actual formula used to manufacture the Chewable Tablets, and their special position of confidence and trust as companies permitted to sell pharmaceuticals in the United States, as well as their disclosure to formularies and the Food and Drug Administration of the fluoride content of the Chewable Tablets with the intent that this information would be relied upon by those paying for them, the reliance of Plaintiff and the Class on Defendants' representations was anticipated, desired, intended, and justified.

47. Given Defendants' market share in this category, Defendants' sub-potent

Chewable Tablets led to widespread under-delivery of fluoride from 2007 through late 2013. That is, dentists, physicians, and pharmacists believed that the Qualitest Chewable Tablets (both Qualitest-branded and PTC-branded) contained the amount of fluoride ion claimed on the label but, in reality, they did not.

48. Defendants cannot argue that the dosage of "fluoride" on the label means "sodium fluoride." First, their admissions in the Stipulation belie any such argument. Further, given the ADA-AAP Guidelines, recommending 1.0 mg, 0.5 mg, or 0.25 mg of fluoride ion, respectively, no rational dentist or doctor would prescribe a 1.0 mg tablet of "sodium fluoride." In that event, a child prescribed the 1.0 mg Qualitest Chewable Tablet would be required to consume 2.2 tablets to meet the ADA-AAP Guidelines. The "INDICATIONS AND USAGE" set forth in Exhibit B make clear that Defendants did not intend for children to take 2.2 tablets to reach the correct dosage of fluoride ion.

49. In the Stipulation, Defendants admitted, acknowledged, and accepted responsibility for the fact that as a result, children who were prescribed Qualitest Chewable Tablets in accordance with the recommendations of the ADA-AAP Guidelines discussed above (taking into account the pertinent variables including fluoridation of drinking water and age) and consumed one Qualitest Chewable Tablet per day, as the product labeling instructed, received in any given tablet approximately 45% of the fluoride ion recommended by the ADA-AAP.

50. These children were, as a result, exposed to an increased risk for developing tooth cavities.

The Plaintiff Is Prescribed Chewable Tablets

51. Ms. Mahoney is the mother of two children, B.M. and R.M., and lives in Orange County, New York. Ms. Mahoney's children were prescribed fluoride supplements when they

were infants. Ms. Mahoney first began giving her children fluoride supplements in the form of drops.

52. When the children became approximately eighteen months old, Ms. Mahoney's pediatrician recommended that the children continue with the fluoride supplements but switch from drops to chewable tablets. Ms. Mahoney's pediatrician wrote out a prescription for generic chewable multivitamins with fluoride specifying the amount of fluoride content to be contained in the multivitamin but not a particular manufacturer.

53. When the children were younger, the pediatrician would prescribe chewable multivitamins with 0.5 mg of fluoride. As the children grew older, the pediatrician increased the dosage amount of fluoride in the chewable multivitamins from 0.5 mg to 1 mg of fluoride.

54. Ms. Mahoney's pediatrician would write generic prescriptions for chewable multivitamins with fluoride specifying the fluoride content – either 0.5 mg or 1 mg. The prescriptions were written for a several month supply of the multivitamins with fluoride. Ms. Mahoney would take the prescription to her local pharmacy where she would have the prescription filled.

55. Upon receiving the prescription, the pharmacist at the local pharmacy would fill Ms. Mahoney's prescription with Defendants' Chewable Tablets with either the 0.5 mg or 1 mg of fluoride depending on what was stated in the prescription. The pharmacist filled the prescription with the Chewable Tablets relying on the amount of fluoride listed on the Defendants' label in order to correctly fill the prescription.

56. Each time Ms. Mahoney received her prescriptions for multivitamins with fluoride from the pharmacist, which were filled with Defendants' Chewable Tablets, she would review the label on the prescription bottle to confirm that the amount of fluoride listed was the

amount prescribed by her pediatrician. Ms. Mahoney checked the label for the fluoride content each time because she did not want her children to receive an incorrect dosage of fluoride. Ms. Mahoney relied on the label stating the amount of fluoride in the Chewable Tablets prior to purchasing them and always made sure that it reflected the amount of fluoride prescribed by her pediatrician. Ms. Mahoney purchased and paid for the Chewable Tablets repeatedly during the Class Period, typically in three month intervals. Had Ms. Mahoney known that the Chewable Tablets did not contain the amount of fluoride actually listed on the label she never would have bought the Chewable Tablets for her children.

57. Furthermore, Defendants never told Ms. Mahoney's children's physician, pharmacist, or the Class Members that the Chewable Tablets did not have the amount of fluoride that Defendants claimed they did on their labels, product inserts and public disclosures. In fact, even when Defendants were put on notice that the fact that the Chewable Tablets did not contain the amounts of fluoride that Defendants claimed on their labels was being investigated by the government, the Defendants did not notify anyone and instead kept that information secret in an effort to deceive and mislead physicians, pharmacists, the Plaintiff, and the Class Members. Ms. Mahoney only learned that Defendants misrepresented the amount of fluoride in the Chewable Tablets in December 2015 when the Stipulation was made public.

58. In addition, in the insert that accompanies the Chewable Tablets, Defendants recognized only one side effect that could result from taking Chewable Tablets. Specifically, Defendants warned that "[a]llergic rash and other idiosyncrasies have been rarely reported." (Ex. B). Even though they knew that the Chewable Tablets did not contain the represented amount of fluoride, Defendants never corrected its insert or its labels in order to warn consumers, the Plaintiff, physicians, pharmacists, or the public at large that the information contained on the

Defendants' label about the fluoride dosage was incorrect and that the Chewable Tablets did not actually contain the amount of fluoride the Defendants claimed.

59. As a direct and proximate result of Defendants' misconduct, Plaintiff and the Class suffered damages and ascertainable losses of money and property by paying for the Chewable Tablets when they would not have if Defendants had not made the misrepresentations about their fluoride content that they did, and by paying more for them, all of which unjustly enriched Defendants.

CLASS ACTION ALLEGATIONS

60. Plaintiff brings this Complaint as a class action pursuant to Federal Rule of Civil Procedure 23.

Class Definitions

61. Plaintiff seeks to represent the following Classes:

> All persons and entities who, during the applicable limitations period, paid for Chewable Tablets manufactured between January 1, 2007 and July 31, 2013, branded "Qualitest Pharmaceuticals," "Vintage Pharmaceuticals," or "Physicians Total Care," purportedly containing doses of fluoride of 1.0 mg, 0.5 mg, or 0.25 mg ("the Class"). Excluded from the Class are Defendants and their officers, directors, agents, and employees, and all governmental entities.

and

> All New York persons and entities who, during the applicable limitations period, paid for Chewable Tablets manufactured between January 1, 2007, and July 31, 2013, branded "Qualitest Pharmaceuticals," "Vintage Pharmaceuticals," or "Physicians Total Care," purportedly containing doses of fluoride of 1.0 mg, 0.5 mg, or 0.25 mg ("New York Subclass"). Excluded from the Class are Defendants and their officers, directors, agents, and employees, and all state and federal governmental entities.

62. The members of the Classes number in the thousands and joinder of all Class Members in a single action is impracticable.

63. This class action is brought pursuant to Rule 23(b)(3) because the questions of

law or fact common to Plaintiff's claims and the Class Members' claims predominate over any question of law or fact affecting only individual Class Members.

64. Defendants have subjected Plaintiff and the members of the Class to the same unfair, unlawful, and deceptive practices and harmed them in the same manner.

Numerosity

65. The individual Class Members are so numerous that joinder of all members in a single action is impracticable. Upon information and belief, there are thousands of members of the Class. For instance, Plaintiff estimates that upwards of 40 million defective Chewable Tablets may have been sold in the twelve-month period running from February 2012 to February 2013, all of which suffered from the same defect. The Class includes all purchasers of Chewable Tablets over a six-year period.

66. Individual Class Members may be identified by reference to objective criteria contained within the Class Definition. Indeed, because the proposed Class is comprised solely of individuals who obtained written physicians' prescriptions for Chewable Vitamins, and those prescriptions were filled at licensed pharmacies, objective and reliable third-party records exist for the identification of all Class Members. For instance, New York law requires that "[r]ecords of all prescriptions filled or refilled shall be maintained for a period of at least five years," and the "records shall indicate [the] date of filling or refilling" as well as the "patient's name and address." N.Y. Educ. Law § 6810(5).

67. In the alternative, based on the relatively low dollar value of individual claims and the correspondingly low risk of fraud or misrepresentation, individual Class Members may self-identify through sworn affidavits or certifications in the post-judgment claims administration process.

Commonality/Predominance

68. Common questions of law and fact exist as to Plaintiff's and the Class Members' claims. These common questions predominate over any questions solely affecting individual Class Members, including but not limited to, the following:

a. Whether Defendants' Chewable Multivitamins with Fluoride contained the concentration of fluoride ion represented on its label and packaging during the Class period;

b. Whether the fact that Defendants' Chewable Multivitamins with Fluoride did not contain the labeled concentration of fluoride ion during the Class period rendered the vitamins valueless; and

c. Whether Defendants were unjustly enriched by virtue of the sale of Chewable Multivitamins with Fluoride that did not contain the labeled concentration of fluoride ion during the Class period.

69. Plaintiff's claims are typical of the Class Members' claims because of the uniformity of Defendants' unlawful conduct. Plaintiff, like all Class Members, was damaged through her payment of money for Chewable Tablets that Defendants falsely claimed to contain certain concentrations of fluoride ion. Instead, Defendants' Chewable Tablets contained only a sub-therapeutic dose of fluoride ion, rendering them clinically and economically valueless.

70. Each Class Member has sustained damages in the same manner as Plaintiff, as a result of Defendants' wrongful conduct.

Adequacy

71. The Plaintiff will fairly and adequately protect and represent the interest of each member of the Class, because she has suffered the same wrongs as the Class Members.

72. Plaintiff is fully cognizant of her responsibilities as Class Representative and has retained the law firms of McCabe Rabin, P.A. and Buckner + Miles to prosecute this case. These law firms are experienced in complex class action litigation, including litigation related to unfair and deceptive trade practices, and have the financial and legal resources to meet the costs of, and understand the legal issues associated with, this type of litigation.

73. Class action treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein, because such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. Moreover, Plaintiff expects that each individual claim for damages will be relatively small, making them extremely inefficient to prosecute individually.

The Prerequisites of Rule 23(b)(3) Are Satisfied

74. The questions of law and fact enumerated above predominate over questions affecting only individual members of the Class, and a class action is the superior method for fair and efficient adjudication of the controversy.

75. The likelihood that individual members of the Class will prosecute separate actions, and their interest in so doing, is small due to the extensive time and considerable expense necessary to conduct such litigation, and the relatively small claims for damages that each of them is likely to have individually.

76. This action will be prosecuted in a fashion to ensure the Court's able management of this case as a class action on behalf of the Class. Plaintiff knows of no difficulty likely to be encountered in the management of this action that would preclude its maintenance as a class

action.

COUNT I
Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

77. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

78. The Chewable Tablets, marketed under the names of Qualitest Pharmaceuticals, Vintage Pharmaceuticals, and Physicians Total Care are consumer products as defined in 15 U.S.C. § 2301(1).

79. Plaintiff and other Class Members are consumers as defined in 15 U.S.C. § 2301(3).

80. Defendants are suppliers and warrantors as defined in 15 U.S.C. § 2301(4) and (5).

81. The Chewable Tablets are "consumer products," as defined in 15 U.S.C. § 2301(1), because they constitute tangible personal property distributed in commerce and are used for personal and family purposes in order to prevent dental caries.

82. Plaintiff and all Class Members purchased Chewable Tablets during the Class Period.

83. In connection with the sale of the Chewable Tablets during the Class period, Defendants issued material statements amounting to warranties as defined in 15 U.S.C. § 2301(6), by representing that the Chewable Tablets contained specified amounts of fluoride ion, including 1 mg, 0.5 mg and 0.25 mg.

84. In fact, the Chewable Tablets did not conform to the above-referenced representations. During the Class period, Defendants manufactured the Chewable Tablets using sodium fluoride as its source of fluoride ion. Sodium fluoride contains roughly 45% fluoride ion.

85. Instead of using 2.2 mg of sodium fluoride as an ingredient to manufacture the 1.0 mg Chewable Tablet, Defendants used only 1.0 mg of sodium fluoride. As such, the 1.0 mg Chewable Tablet contained approximately 0.44 mg of fluoride ion.

86. Instead of using 1.1 mg of sodium fluoride as an ingredient to manufacture the 0.5 mg Chewable Tablet, Defendants used only 0.5 mg sodium fluoride. As such, the 0.5 mg Chewable Tablet contained approximately 0.22 mg of fluoride ion.

87. Instead of using 0.55 mg of sodium fluoride as an ingredient to manufacture the 0.25 mg Chewable Tablet, Defendants used only 0.25 mg sodium fluoride. As such, the 0.25 mg Chewable Tablet contained approximately 0.11 mg of fluoride ion.

88. By breaching its express warranty as to the fluoride ion content of its vitamins, Defendants violated the statutory rights due to Plaintiff and Class Members pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 *et seq.*, thereby damaging Plaintiff and Class members.

89. As a result, Plaintiff and Class Members received Chewable Tablets containing approximately 45% of the recommended daily intake of fluoride ion.

90. Plaintiff and Class Members were injured as a direct and proximate result of Defendants' breach. Plaintiff and the Class Members relied upon warranties by Defendants and would not have purchased the Chewable Tablets manufactured by Defendants, had Defendants disclosed the Chewable Tablets' actual fluoride ion content. Defendants' breach of their warranties caused Plaintiff and the Class damages. The amount of those damages will be determined at trial.

91. Plaintiff and the Class preliminarily raise this claim for the purposes of establishing their representational capacity, pursuant to 15 U.S.C. § 2310(a)(3), (e).

COUNT II
Breach of Express Warranty

92. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

93. The Chewable Tablets were manufactured by Defendants for human consumption.

94. Defendants are and were at all relevant times "merchants" with respect to the sale of the Chewable Tablets under N.Y. UCC Law § 2-104(1) and "sellers" of Chewable Tablets under N.Y. UCC Law § 2-103(1)(d).

95. The Chewable Tablets are and were at all relevant times "goods" under the N.Y. UCC Law, including but not limited to, N.Y. UCC Law §§ 2-105(1).

96. In connection with the sale of the Chewable Tablets, Defendants issued material statements amounting to warranties by representing that: (a) the 1.0 mg Chewable Tablets contained 1.0 mg of fluoride ion; (b) the 0.5 mg Chewable Tablets contained 0.5 mg of fluoride ion; and (c) the 0.25 mg Chewable Tablets contained 0.25 mg of fluoride ion.

97. In fact, the Chewable Tablets in each strength did not conform to the above-referenced representations. Because Defendants used sodium fluoride as the source of fluoride ion for the Chewable Tablets, and because Defendants did not increase the concentration of sodium fluoride to take account of the fact that it contains only 45% fluoride ion, the Chewable Tablets did not, in fact, contain the amount of fluoride ion listed on the bottle.

98. These statements were material to Plaintiff and the Class members and they relied on them. Plaintiff and the Class members would not have paid for the Chewable Tablets had they known that these express warranties were false.

99. Furthermore, these statements were material to purchasers, including the Plaintiff, of children's chewable fluoride tablets. No one would have purchased or paid for the Chewable

Tablets, if the warranties had been known to be false.

100. As set forth above, Defendants were aware of and were repeatedly placed on notice regarding the deficiencies in the Chewable Tablets, including the notice provided by Plaintiff to Defendants, on behalf of herself and the Class, on or about December 17, 2015, when they were provided with a copy of the complaint in this matter.

101. Plaintiff and Class Members were injured and suffered damages as a direct and proximate result of Defendants' breach, because they would not have purchased the Chewable Tablets if Defendants had disclosed the Chewable Tablets' actual fluoride ion content.

COUNT III
Negligent Misrepresentation

102. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

103. Defendants represented that the three strengths of its Chewable Tablets contained 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion, respectively.

104. Defendants misrepresented the fluoride ion content of its Chewable Tablets. During the Class period, Defendants manufactured the Chewable Tablets using sodium fluoride as its source of fluoride ion. Sodium fluoride contains roughly 45% fluoride ion, but Defendants did not use 2.2 mg, 1.1 mg, and 0.55 mg of sodium fluoride, respectively, to reach the appropriate concentration of fluoride ion in the Chewable Tablets.

105. Defendants had a duty to disclose the correct actual amount of fluoride ion in the Chewable Tablets. Defendants assumed the duty to disclose the fluoride ion content of the Chewable Tablets by labeling each package with a "dosage" in line with the ADA-AAP Guidelines. By misrepresenting the actual fluoride ion content, Defendants breached their duty to Plaintiff and Class Members.

106. As set forth above, Defendants possess unique and specialized expertise with

regard to the manufacture of pharmaceuticals including the Chewable Tablets, and with respect to their fluoride ion content. Defendants also had a special relationship with Plaintiff and the Class Members. As a result, Defendants had a duty to impart correct information about the Chewable Tablets to Plaintiff and the Class.

107. Defendants also knew that the Chewable Tablets were destined to be consumed by children and that Plaintiff and the Class Members would use the Chewable Tablets for the particular purpose of providing supplemental fluoride to children. Defendants, by representations to, among others, Plaintiff and the Class Members, pharmacists, formularies such as Golden Rule, and the United States Food and Drug Administration, intended to cause Plaintiff and the Class to rely on Defendants' representations about the fluoride ion content of the Chewable Tablets. Through the distribution of these representations through channels that Defendants knew would be trusted by Plaintiff and Class Members, Defendants established a special relationship with them that in turn established a duty to give correct information.

108. Defendants intended to induce, and did induce, Plaintiff and Class members to purchase the Chewable Tablets based on Defendants' representations of the fluoride ion content. Defendants knew that Plaintiff and the Class Members relied on their representations about the fluoride ion content of the Chewable Tablets for a serious purpose, namely, the dental health of their children.

109. Plaintiff and Class Members reasonably and justifiably relied on Defendants' representations of the fluoride ion content of the Chewable Tablets.

110. Plaintiff and Class Members would not have purchased the Chewable Tablets if Defendants had correctly represented the actual fluoride ion content. No reasonable consumer would have purchased a subtherapeutic (and likely worthless) dose of medication.

COUNT IV
Unjust Enrichment

111. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

112. Plaintiff and Class members conferred benefits on Defendants by purchasing the Chewable Tablets manufactured by Defendants.

113. Defendants knowingly and voluntarily accepted and retained the financial benefit conferred by Plaintiff and Class Members.

114. Defendants have been unjustly enriched by retaining the revenues derived from Plaintiff's and Class Members' purchases of and payments for the Chewable Tablets. Retention of those revenues is unjust because Defendants misrepresented that the 1.0 mg Chewable Tablet contained 1.0 mg of fluoride ion, when in fact the 1.0 mg Chewable Tablet contained 0.44 mg of fluoride ion. Likewise, the 0.5 mg Chewable Tablet actually contained only 0.22 mg of fluoride ion, and the 0.25 mg Chewable Tablet contained only 0.11 mg of fluoride ion. As a result of the lower concentrations of fluoride ion, the Chewable Tablets were effectively worthless to Plaintiff and Class Members.

115. Defendants will be unjustly enriched if permitted to retain the aforementioned benefits, and Plaintiff and Class Members are entitled to recover the amount by which Defendants were unjustly enriched at their expense. It is against equity and good conscience to permit Defendants to retain the money paid by Plaintiff and Class Members for the Chewable Tablets.

COUNT V
New York General Business Law § 349

116. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

117. New York General Business Law § 349, prohibits "[d]eceptive acts or practices in

the conduct of any business, trade or commerce or in the furnishing of any service[.]"

118. Defendants violated the New York General Business Law by misrepresenting the fluoride ion content of their Chewable Tablets to consumers, including Plaintiff, and thereby engaged in deceptive, misleading and material consumer-oriented conduct. Instead of using 2.2 mg of sodium fluoride as an ingredient to manufacture the 1.0 mg Chewable Tablet, Defendants used only 1 mg of sodium fluoride, leading to a tablet containing only 0.44 mg of fluoride ion. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg tablet and 0.55 mg of sodium fluoride for the 0.25 mg tablet, Defendants used 0.5 mg and 0.25 mg of sodium fluoride, respectively, leading to tablets with only 0.22 mg and 0.11 mg of fluoride ion, respectively.

119. Defendants' misrepresentation of the fluoride content of the Chewable Tablets was likely to deceive a reasonable consumer acting reasonably under the circumstances. Defendants' representations that their Chewable Tablets contained specific concentrations of fluoride, in line with the ADA-AAP Guidelines, induced an objectively reasonable expectation that the tablets contained those recommended concentrations of fluoride ion. That representation was made every time the Chewable Tablets were dispensed, by means of the label on the prescription container holding the Chewable Tables and the insert accompanying it, both of which, among other things, stated the fluoride ion dosage. Plaintiff saw that misleading representation each time she went to the pharmacy to obtain the Chewable Tables for her children, and accepted and paid for the Chewable Tables only after confirming that the dosage stated on the label matched the dosage prescribed by her childrens' physician.

120. Defendants' misrepresentation of the fluoride ion content of the Chewable Tablets was material.

121. As a direct and proximate result of Defendants' New York General Business Law

violations, Plaintiff and the New York Subclass Members suffered actual damages in that, among other things, Plaintiff paid a premium for the Chewable Tablets based on Defendants' misrepresentations.

COUNT VI
Breach of Implied Warranty Of Merchantability

122. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

123. Defendants are and were at all relevant times "merchants" with respect to the sale of the Chewable Tablets under N.Y. UCC Law § 2-104(1) and "sellers" of Chewable Tablets under N.Y. UCC Law § 2-103(1)(d).

124. The Chewable Tablets are and were at all relevant times "goods" under the N.Y. UCC Law, including but not limited to, N.Y. UCC Law §§ 2-105(1).

125. At the time Plaintiff and the Class purchased and paid for the Chewable Tablets, Defendants knew the particular purpose for which the Chewable Tablets were required, namely, to provide supplement fluoride. Indeed, the product label and product insert state the fluoride ion content and make reference to the ADA-AAP Guidelines. Defendants also knew that Plaintiffs and the Class were relying on their skill and judgment to furnish suitable goods for the purpose to which Defendants knew they were to be put. Plaintiff and the Class Members relied on Defendants skill and judgment, specifically with regard to the manufacture of the Chewable Tablets.

126. A warranty that the Chewable Tablets were in a merchantable condition and fit for the ordinary purpose for which multivitamins are manufactured for is implied by law pursuant to the N.Y. UCC Law, including but not limited to, N.Y. UCC Law §§ 2-314 and 2A-212.

127. The Chewable Tablets, when manufactured, sold, and at all times thereafter, were

not in merchantable condition and are not fit for the ordinary purpose for which the Chewable Tablets are used. Specifically, the Chewable Tablets are inherently defective in that they do not have the amount of fluoride ion represented on the label and packaging insert.

128. The Defendants were provided notice that the Chewable Tablets did not actually contain the amount of fluoride ion claimed through the *qui tam* lawsuit that led to the Complaint-in-Intervention and the Stipulation, as well as by the Plaintiff's Complaint herein.

129. As a direct and proximate result of the Defendants' breach of the implied warranty of merchantability, the Plaintiff has suffered damages in an amount to be proven at trial.

COUNT VII
Fraud

130. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

131. Defendants made material representations to Plaintiff, the Class Members, physicians, pharmacists, formularies, and the United States Food and Drug Administration regarding the fluoride ion content of the Chewable Tablets.

132. Those representations were false. Defendants knew they were false and made them with the intention to deceive Plaintiff and the Class.

133. Defendants knew the master formulas by which the Chewable Tablets were produced, and knew that they could not yield the represented amount of fluoride ion. Nonetheless, as set forth above, Defendants disseminated information and representations to Plaintiff, the Class Members, physicians, pharmacists, formularies, and the United States Food and Drug Administration regarding the fluoride ion content of the Chewable Tablets.

134. Plaintiff and the Class Members believed the representations to be true and justifiably relied on them, and were deceived. As a direct and proximate result, Plaintiff and the

Class suffered damages in an amount to be determined at trial.

COUNT VIII
Fraudulent Concealment

135. Plaintiff re-alleges paragraphs 1 through 76 as if fully set forth herein.

136. Defendants made material representations to Plaintiff, the Class Members, physicians, pharmacists, formularies, and the United States Food and Drug Administration regarding the fluoride content of the Chewable Tablets.

137. Those representations were false. Defendants knew they were false and made them with the intention to deceive Plaintiff and the Class.

138. Defendants knew the master formulas by which the Chewable Tablets were produced, and knew that they could not yield the represented amount of fluoride ion. Nonetheless, as set forth above, Defendants disseminated information and representations to Plaintiff, the Class Members, physicians, pharmacists, formularies, and the United States Food and Drug Administration regarding the fluoride ion content of the Chewable Tablets.

139. Defendants had a duty to disclose the truth about the Chewable Tablets.

140. Plaintiff and the Class Members believed the representations to be true and justifiably relied on them, and were deceived. As a direct and proximate result, Plaintiff and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

Plaintiff, on behalf of herself and the Class, request the following relief:

a. Certification of the Class;

b. A jury trial and judgment against all Defendants;

c. The cost of suit, including reasonable attorneys' fees;

d. General, actual, special, statutory, and compensatory damages in an amount to be

determined;

e. Pre-judgment and post-judgment interest at the maximum rate permitted by applicable law; and

f. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury for all claims so triable, pursuant to Fed.R.Civ.P. 38(b).

Dated: March 18, 2016

Respectfully submitted,

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Counsel for Plaintiff

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 18, 2016 the foregoing document was served via the Court's CM/ECF portal to all counsel of record identified on the attached Service List.

/s Robert C. Glass
Robert C. Glass
S.D.N.Y. Bar Code: RG0217

SERVICE LIST
Shannon Mahoney
v.
Endo Health Solutions, Inc., et al.
U.S. District Court, Southern District of New York
No. 15-09841-CIV-DLC

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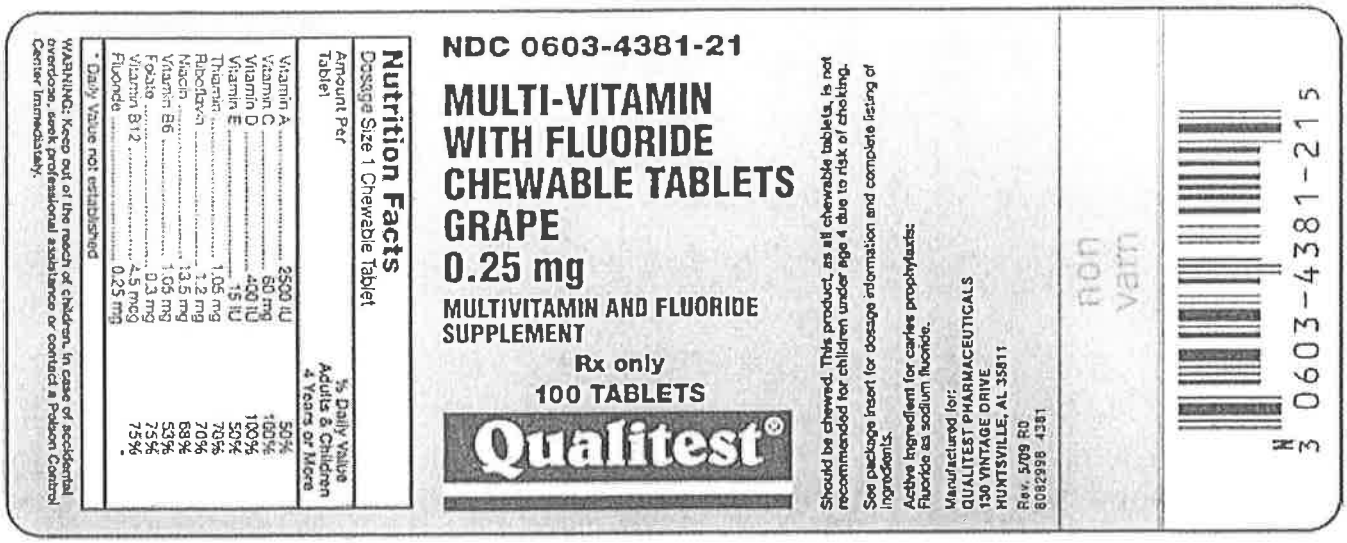
PRINCIPAL DISPLAY PANEL



PRINCIPAL DISPLAY PANEL

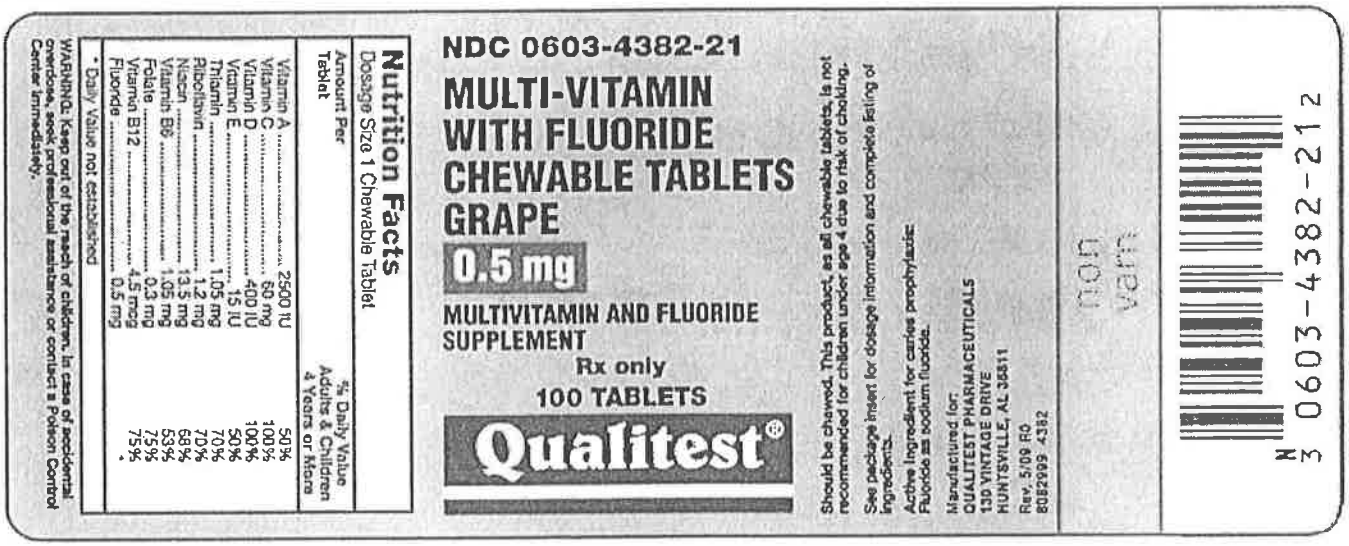


EXHIBIT
tabbies
A

PRINCIPAL DISPLAY PANEL

MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE

Rx only

Nutrition Facts
Dosage Size 1 Chewable Tablet

Amount Per Tablet	1 mg	0.5 mg	0.25 mg	%DV Adults and Children 4 Years or More
Vitamin A	2500 IU	2500 IU	2500 IU	50%
Vitamin C	60 mg	60 mg	60 mg	100%
Vitamin D	400 IU	400 IU	400 IU	100%
Vitamin E	15 IU	15 IU	15 IU	50%
Thiamin	1.05 mg	1.05 mg	1.05 mg	70%
Riboflavin	1.2 mg	1.2 mg	1.2 mg	70%
Niacin	13.5 mg	13.5 mg	13.5 mg	68%
Vitamin B6	1.05 mg	1.05 mg	1.05 mg	53%
Folate	0.3 mg	0.3 mg	0.3 mg	75%
Vitamin B12	4.5 mcg	4.5 mcg	4.5 mcg	75%
Fluoride	1 mg	0.5 mg	0.25 mg	*

*Daily Value (DV) not established

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Other Ingredients: Artificial grape flavor, ascorbic acid, cholecalciferol, compressible sugar, D&C Red #7 calcium lake, FD&C Blue #1 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, niacinamide, polyethylene glycol, pyridoxine, riboflavin, sodium ascorbate, stearic acid, thiamine, vitamin A acetate, vitamin B12 and vitamin E acetate.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries.

Multivitamin with Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a *topical* as well as *systemic* source of fluoride.

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the *hydroxyapatite* in the tooth as it is formed to produce the more caries-resistant crystal, *fluorapatite*. The reaction may be expressed by the equation:

$$\underset{\text{(Hydroxyapatite)}}{Ca_{10}(PO_4)_6(OH)_2} + 2F^- \longrightarrow \underset{\text{(Fluorapatite)}}{Ca_{10}(PO_4)_6F_2} + 2OH^-$$

Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
3. After eruption, the surface enamel acquires fluoride from the water, food, supplementary fluoride and smaller amounts from saliva.

INDICATIONS AND USAGE

Supplementation of the diet with ten essential vitamins.

Supplementation of the diet with fluoride for caries prophylaxis.

Multivitamin with 1 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.

Multivitamin with 0.5 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with 0.25 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with Fluoride Chewable Tablets supply significant amounts of Vitamins A, C, D, E, thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, children obtain ten essential vitamins *and the important* mineral, fluoride.

The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

Children using Multivitamin with Fluoride Chewable Tablets regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

WARNING

As in the case of all *medications*, keep out of the reach of children.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking.

PRECAUTIONS

The suggested dose of Multivitamin with Fluoride Chewable Tablets *should not be exceeded*, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing Multivitamin with Fluoride Chewable Tablets:

1. Determine the fluoride content of the drinking water from all major sources.
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.
3. Periodically check to make sure that the child does not develop significant dental fluorosis.

Do not eat or drink dairy products within one hour of medication administration.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

DOSAGE AND ADMINISTRATION

One tablet daily or as prescribed.

HOW SUPPLIED

Multivitamin with 1 mg, 0.5 mg and 0.25 mg Fluoride Chewable Tablets Grape are all available in 100 tablet bottles.

Manufactured for:
QUALITEST PHARMACEUTICALS
130 Vintage Drive
Huntsville, AL 35811

8183001
Rev 03/11
R2

8183001 R2

MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE

Rx only

EXHIBIT
tabbies
B

MULTI VITAMIN WITH FLUORIDE tablet, chewable [Physicians Total Care, Inc.]

RxNorm Names
▸ Review RxNorm Normal Forms

Permanent Link:
http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=2407983c-bd99-4754-9cb2-cdda7955168c

Category	DEA Schedule	Marketing Status
HUMAN PRESCRIPTION DRUG LABEL		unapproved drug other

NOTE: THIS DRUG HAS NOT BEEN FOUND BY FDA TO BE SAFE AND EFFECTIVE, AND THIS LABELING HAS NOT BEEN APPROVED BY FDA. For further information about unapproved drugs, click here.

Drug Label Sections
Description | Clinical Pharmacology | Indications & Usage | Contraindications | Warnings
Precautions | Adverse Reactions | Overdosage | Dosage & Administration | How Supplied
Patient Counseling Information | Supplemental Patient Material | Boxed Warning | Patient Package Insert
Highlights | Full Table of Contents | Medication Guide

Nutrition Facts
Dosage Size 1 Chewable Tablet

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Vitamin D	400 IU	400 IU	400 IU	100%
Vitamin E	15 IU	15 IU	15 IU	50%
Thiamin	1.05 mg	1.05 mg	1.05 mg	70%
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Niacin	13.5 mg	13.5 mg	13.5 mg	68%
Vitamin B6	1.05 mg	1.05 mg	1.05 mg	53%
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Vitamin B12	4.5 mcg	4.5 mcg	4.5 mcg	75%
Fluoride	1 mg	0.5 mg	0.25 mg	*

*Daily Value (DV) not established

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Other Ingredients:

Artificial grape flavor, ascorbic acid, cholecalciferol, compressible sugar, D&C Red #7 calcium lake, FD&C Blue #1 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, niacinamide, polyethylene glycol, pyridoxine, riboflavin, sodium ascorbate, stearic acid, thiamine, vitamin A acetate, vitamin B12 and vitamin E acetate.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries.

Multivitamin with Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a

chewable tablet. Because the tablets are chewable, they provide a *topical* as well as *systemic* source of fluoride.

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the *hydroxyapatite* in the tooth as it is formed to produce the more caries-resistant crystal, *fluorapatite*. The reaction may be expressed by the equation:

$$\underset{\text{(Hydroxyapatite)}}{Ca_{10}(PO_4)_6(OH)_2} + 2F^- \longrightarrow \underset{\text{(Fluorapatite)}}{Ca_{10}(PO_4)_6F_2} + 2OH^-$$

Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
3. After eruption, the surface enamel acquires fluoride from the water, food, supplementary fluoride and smaller amounts from saliva.

INDICATIONS AND USAGE

Supplementation of the diet with ten essential vitamins.

Supplementation of the diet with fluoride for caries prophylaxis.

Multivitamin with 1 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.

Multivitamin with 0.5 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with 0.25 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with Fluoride Chewable Tablets supply significant amounts of Vitamins A, C, D, E, thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, children obtain ten essential vitamins and the important mineral, fluoride.

The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

Children using Multivitamin with Fluoride Chewable Tablets regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

WARNING

As in the case of all medications, keep out of the reach of children.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking.

PRECAUTIONS

The suggested dose of Multivitamin with Fluoride Chewable Tablets *should not be exceeded*, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing Multivitamin with Fluoride Chewable Tablets:

1. Determine the fluoride content of the drinking water from all major sources.
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.
3. Periodically check to make sure that the child does not develop significant dental fluorosis.

Do not eat or drink dairy products within one hour of medication administration.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

DOSAGE AND ADMINISTRATION

One tablet daily or as prescribed.

HOW SUPPLIED

Multivitamin with 1 mg, 0.5 mg and 0.25 mg Fluoride Chewable Tablets Grape are all available in

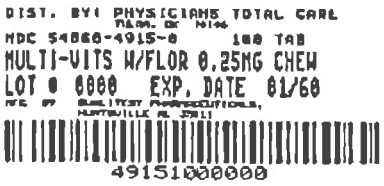
1 mg	
Bottles of 30	NDC 54868-1313-1
Bottles of 100	NDC 54868-1313-0
0.5 mg	
Bottles of 30	NDC 54868-4914-1
Bottles of 100	NDC 54868-4914-0
0.25 mg Bottles of 100	NDC 54868-4915-0

Manufactured for:
QUALITEST PHARMACEUTICALS
130 Vintage Drive
Huntsville, AL 35811

8183001
R03/11-R2

Relabelling and Repackaging by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

PRINCIPAL DISPLAY PANEL



PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL

MULTI VITAMIN WITH FLUORIDE

multi vitamin with fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-4915 (NDC:0603-4381)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	SODIUM FLUORIDE	0.25 mg
VITAMIN A ACETATE (VITAMIN A)	VITAMIN A ACETATE	2500 [IU]
ASCORBIC ACID (ASCORBIC ACID)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (ASCORBIC ACID)	SODIUM ASCORBATE	36 mg
CHOLECALCIFEROL (CHOLECALCIFEROL)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (.ALPHA.-TOCOPHEROL ACETATE, DL-)	.ALPHA.-TOCOPHEROL ACETATE, DL-	15 [IU]
THIAMINE MONONITRATE (THIAMINE)	THIAMINE MONONITRATE	1.05 mg
RIBOFLAVIN (RIBOFLAVIN)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (NIACINAMIDE)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (PYRIDOXINE)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
FOLIC ACID (FOLIC ACID)	FOLIC ACID	0.3 mg
CYANOCOBALAMIN (CYANOCOBALAMIN)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR	
D&C RED NO. 7	
FD&C BLUE NO. 1	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL	
STEARIC ACID	

Product Characteristics

Color	PURPLE	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	4378;V
Contains			

Packaging

#	Item Code	Package Description	Multilevel Packaging
1	NDC:54868-4915-0	100 TABLET, CHEWABLE (100 TABLET) in 1 BOTTLE, PLASTIC	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/05/2003	

MULTI VITAMIN WITH FLUORIDE

multi vitamin with fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-4914 (NDC:0603-4382)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	SODIUM FLUORIDE	0.5 mg
VITAMIN A ACETATE (VITAMIN A)	VITAMIN A ACETATE	2500 [iU]
ASCORBIC ACID (ASCORBIC ACID)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (ASCORBIC ACID)	SODIUM ASCORBATE	36 mg
CHOLECALCIFEROL (CHOLECALCIFEROL)	CHOLECALCIFEROL	400 [IU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (.ALPHA.-TOCOPHEROL ACETATE, DL-)	ALPHA -TOCOPHEROL ACETATE, DL-	15 [iU]
THIAMINE MONONITRATE (THIAMINE)	THIAMINE MONONITRATE	1.05 mg
RIBOFLAVIN (RIBOFLAVIN)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (NIACINAMIDE)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (PYRIDOXINE)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
FOLIC ACID (FOLIC ACID)	FOLIC ACID	0.3 mg
CYANOCOBALAMIN (CYANOCOBALAMIN)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR	
D&C RED NO. 7	
FD&C BLUE NO. 1	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL	
STEARIC ACID	

Product Characteristics

Color	PURPLE	Score	no score
Shape	SQUARE	Size	10mm
Flavor	GRAPE	Imprint Code	4379;V
Contains			

Packaging

#	Item Code	Package Description	Multilevel Packaging
1	NDC:54868-4914-0	100 TABLET, CHEWABLE (100 TABLET) in 1 BOTTLE, PLASTIC	None
2	NDC:54868-4914-1	30 TABLET, CHEWABLE (TABLET) in 1 BOTTLE	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/08/2003	

MULTI VITAMIN WITH FLUORIDE

multi vitamin with fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:54868-1313 (NDC:0603-4383)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	SODIUM FLUORIDE	1 mg
VITAMIN A ACETATE (VITAMIN A)	VITAMIN A ACETATE	2500 [iU]
ASCORBIC ACID (ASCORBIC ACID)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (ASCORBIC ACID)	SODIUM ASCORBATE	36 mg
CHOLECALCIFEROL (CHOLECALCIFEROL)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (.ALPHA.-TOCOPHEROL ACETATE, DL-)	.ALPHA.-TOCOPHEROL ACETATE, DL-	15 [iU]
THIAMINE MONONITRATE (THIAMINE)	THIAMINE MONONITRATE	1.05 mg
RIBOFLAVIN (RIBOFLAVIN)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (NIACINAMIDE)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (PYRIDOXINE)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
FOLIC ACID (FOLIC ACID)	FOLIC ACID	0.3 mg
CYANOCOBALAMIN (CYANOCOBALAMIN)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR	
D&C RED NO. 7	
FD&C BLUE NO. 1	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOL	
STEARIC ACID	

Product Characteristics

Color	PURPLE	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	4380;V
Contains			

Packaging

#	Item Code	Package Description	Multilevel Packaging
1	NDC:54868-1313-0	100 TABLET, CHEWABLE (100 TABLET) in 1 BOTTLE, PLASTIC	None
2	NDC:54868-1313-1	30 TABLET, CHEWABLE (TABLET) in 1 BOTTLE	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/04/2003	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Operations
Physicians Total Care, Inc.		194123980	relabel, repack

Revised: 04/2012

Physicians Total Care, Inc.