Commission is adjusting this penalty from $11,000 to $12,100.[13]

In addition, the FTC is adjusting civil penalties under section 814(a) of the Energy Independence and Security Act of 2007 (''EISA'')[14] The CPI–U has increased from 208.352 in June 2007 to 233.504 in June 2013, or 12.1%. Applying this percentage increase and the FCPIAA's ten percent cap on initial adjustments, this penalty will increase from $1,000,000 to $1,100,000.

To reflect these adjustments, the FTC is amending Commission Rule 1.98 by modifying paragraphs (b) and (f)–(l), adding new paragraphs (n)–(o), and redesignating current paragraph (n) as paragraph (p). These changes take effect on April 10, 2014.

Procedural Requirements

Under the Administrative Procedure Act (''APA''), a final rule may be issued without public notice and comment if an agency finds good cause that notice and comment are impractical, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(3)(B). Because the Commission must adjust its civil penalties according to a statutory formula, the Commission finds that good cause exists to forego public notice and comment under the APA. *Id.* Because these adjustments are mandated by statute and do not involve the exercise of Commission discretion or any policy judgments, public notice and comment is unnecessary. For this reason, the requirements of the Regulatory Flexibility Act (''RFA'') also do not apply.[15] Finally, this rule does not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995 as amended. 44 U.S.C. 3501 *et seq.*

List of Subjects for 16 CFR Part 1

Administrative practice and procedure, Penalties, Trade practices.

For the reasons set forth in the preamble, the Federal Trade Commission amends Title 16, chapter I, subchapter A, of the Code of Federal Regulations, as follows:

PART 1—GENERAL PROCEDURES

Subpart L—[Amended]

■ 1. The authority citation for subpart L continues to read as follows:

Authority: 28 U.S.C. 2461 note.

■ 2. Revise § 1.98 to read as follows:

§ 1.98 Adjustment of civil monetary penalty amounts.

This section makes inflation adjustments in the dollar amounts of civil monetary penalties provided by law within the Commission's jurisdiction. The following civil penalty amounts apply to violations occurring after April 10, 2014.

(a) Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1)—$16,000;

(b) Section 11(l) of the Clayton Act, 15 U.S.C. 21(l)—$8,500;

(c) Section 5(l) of the FTC Act, 15 U.S.C. 45(l)—$16,000;

(d) Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. 45(m)(1)(A)—$16,000;

(e) Section 5(m)(1)(B) of the FTC Act, 15 U.S.C. 45(m)(1)(B)—$16,000;

(f) Section 10 of the FTC Act, 15 U.S.C. 50—$210;

(g) Section 5 of the Webb-Pomerene (Export Trade) Act, 15 U.S.C. 65—$210;

(h) Section 6(b) of the Wool Products Labeling Act, 15 U.SC. 68d(b)—$210;

(i) Section 3(e) of the Fur Products Labeling Act, 15 U.S.C. 69a(e)—$210;

(j) Section 8(d)(2) of the Fur Products Labeling Act, 15 U.S.C. 69f(d)(2)—$210;

(k) Section 333(a) of the Energy Policy and Conservation Act, 42 U.S.C. 6303(a)—$210;

(l) Sections 525(a) and (b) of the Energy Policy and Conservation Act, 42 U.S.C. 6395(a) and (b), respectively—$8,500 and $16,000, respectively;

(m) Section 621(a)(2) of the Fair Credit Reporting Act, 15 U.S.C. 1681s(a)(2)—$3,500;

(n) Section 1115(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108–173, 21 U.S.C. 355 note—$12,100;

(o) Section 814(a) of the Energy Independence and Security Act of 2007, 42 U.S.C. 17304—$1,100,000; and

(p) Civil monetary penalties authorized by reference to the Federal Trade Commission Act under any other provision of law within the jurisdiction of the Commission—refer to the amounts set forth in paragraphs (c), (d), (e) and (f) of this section, as applicable.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014–05266 Filed 3–10–14; 8:45 am]

BILLING CODE 6750–01–P

[13] 28 U.S.C.2461 note (citing Pub. L. 104–134, section 31001(s)(2), 110 Stat. 1321, 1373 (1996)).

[14] The Commission determined in 2009 that its civil penalty authority under EISA was too recent to warrant adjustment for inflation. 74 FR at 858.

[15] A regulatory flexibility analysis under the RFA is required only when an agency must publish a notice of proposed rulemaking for comment. *See* 5 U.S.C. 603.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2009–F–0570]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_2 Bakers Yeast

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections.

SUMMARY: The Food and Drug Administration (FDA or we) is responding to objections that we have received on the final rule that amended the food additive regulations authorizing the use of vitamin D_2 bakers yeast as a source of vitamin D_2 and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 International Units (IU) of vitamin D_2 per 100 grams (g) in the finished food. After reviewing the objections to the final rule, FDA has concluded that they do not provide a basis for amending or revoking the regulation.

DATES: Effective date confirmed: August 29, 2012.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of December 17, 2009 (74 FR 66979), FDA published a notice announcing the filing of a food additive petition (FAP 9A4779) submitted by Lallemand, Inc., c/o Dennis T. Gordon, 117 N. Welcome Slough Rd., Puget Island, Cathlamet, WA 98612. The petition proposed to amend the food additive regulations in part 172, *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172), to provide for the safe use of vitamin D_2 bakers yeast as a dual purpose nutrient supplement and leavening agent or dough relaxer in yeast-containing baked products at levels not to exceed 400 IU of vitamin D_2 per 100 g in the finished food. The specific foods identified in the petition were yeast-leavened baked goods and baking mixes, and yeast-leavened baked snack foods. After the notice was published, Lallemand amended the petition to exclude the proposed use of the additive as a dough relaxer.

In response to FAP 9A4779, we issued a final rule in the **Federal Register** on August 29, 2012 (77 FR 52228), authorizing the safe use of vitamin D_2 bakers yeast as a source of vitamin D_2 and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D_2 per 100 g in the finished food. This regulation is codified at § 172.381. We based our decision on data contained in the petition and in our files. The preamble to the final rule (77 FR 52228 at 52231) stated that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by September 28, 2012).

II. Objections and Requests for a Hearing

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, ''specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections.''

Under § 171.110 (21 CFR 171.110), objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the final rule authorizing the use of vitamin D_2 bakers yeast as a source of vitamin D_2 and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D_2 per 100 g in the finished food, we received a letter from AB Mauri North America (AB Mauri) (letter to Docket No. FDA–2009–F–0570, September 26, 2012) containing two objections. The letter from AB Mauri did not request a hearing on either objection. Therefore, AB Mauri has waived its right to a hearing on those objections (see § 12.22(a)(4)). The only remaining question under § 12.24(a) is whether AB Mauri's objections, and the information submitted in support of the objections, establish that the regulation authorizing the use of vitamin D_2 bakers yeast should be modified or revoked. As discussed in detail in section III, we have concluded that AB Mauri has not established a basis for modification or revocation of the regulation authorizing the use of vitamin D_2 bakers yeast.

III. Analysis of Objections

The first objection raised by AB Mauri contends that the regulation authorizing the use of vitamin D_2 bakers yeast in food (§ 172.381) is based on the incorrect assumptions that: (1) vitamin D_2 bakers yeast can be produced in such a way that the vitamin D_2 levels in the yeast itself can be accurately controlled and declared; and (2) vitamin D_2 bakers yeast can be used by food manufacturers in a way that allows them to control the level of vitamin D_2 in the finished product and accurately declare its level on the labeling of the finished food product. AB Mauri asserts that these assumptions may result in vitamin D_2 levels in finished products that exceed the maximum level specified in the regulation and declaration of inaccurate vitamin D_2 levels on finished product nutrition labels.

In support of their claim, AB Mauri presents vitamin D_2 levels from a limited number of samples of Lallemand's commercially available vitamin D_2 bakers yeast that AB Mauri had analyzed by an independent laboratory. According to AB Mauri, the results of the independent analysis demonstrate that the actual amount of vitamin D_2 in bakers yeast varies, and does not necessarily reflect the level of vitamin D_2 that Lallemand claims on its Web site is ''typical'' for the product. AB Mauri also provides theoretical ranges of vitamin D_2 levels that could result in batches of the same size product, depending on the level and type of vitamin D_2 bakers yeast used. According to AB Mauri, using different levels and types of vitamin D_2 bakers yeast result in different levels of vitamin D_2 in batches of equal size.

However, AB Mauri did not provide the manufacturer's certificates of analysis so that the vitamin D_2 levels of the analyzed samples could be verified. Additionally, AB Mauri did not identify the analytical method used in the analyses of vitamin D_2 bakers yeast and did not provide information on the samples that were analyzed (e.g., lot numbers, number of samples and replicates analyzed, age of samples, sample storage conditions, or solid content of the yeast cream samples). Therefore, the information provided by AB Mauri is not sufficient to demonstrate that there was a difference in the analyzed vitamin D_2 levels and the vitamin D_2 levels which Lallemand claims is typical for the product.

The information provided by AB Mauri also does not provide sufficient evidence showing levels of vitamin D_2 in finished baked products made with vitamin D_2 bakers yeast exceed the maximum permitted level since the levels of vitamin D_2 in the finished baked products are based on hypothetical percentages of yeast used. Therefore, this objection does not provide a basis for FDA to reconsider its decision to issue the final rule on vitamin D_2 bakers yeast.

Our review of the petition explicitly considered variability of vitamin D_2 in ultraviolet light-treated bakers yeast. The petitioner provided analytical data of vitamin D_2 levels from production lots of vitamin D_2 bakers yeast, including the certificates of analysis for the products analyzed. Results demonstrated that vitamin D_2 levels were at least equal to 80 percent of the value for vitamin D_2 declared on the label of the vitamin D_2 bakers yeast product (see 21 CFR 101.9(g)(4)(ii)). Additionally, certificates of analysis, which include vitamin D_2 levels in the product, are provided with each product sold, thus allowing bakers to calculate the amount of vitamin D_2 that each finished product will contain. Based on these data and other information provided in the petition, we concluded that there are adequate controls in place to ensure that vitamin D_2 bakers yeast may be used in conformance with the provisions in the regulation.

Section 409 of the FD&C Act requires that a regulation authorizing the use of a food additive must prescribe, with respect to the proposed uses of the additive, the conditions under which the additive may be safely used. Section 172.381, as established in the final rule, does not include a requirement to label finished food with the level of vitamin D_2 contained in the finished food. However, to ensure that the level of vitamin D_2 in the finished food does not exceed the maximum level specified in the regulation, § 172.381(d) states that the label or labeling of the food additive container must bear, in addition to the other information required by the FD&C Act, adequate directions for use to provide a final product that complies with the limitations prescribed in § 172.381(c) (under which the additive may be used in yeast-leavened baked goods and baking mixes and yeast-

leavened baked snack foods at levels not to exceed 400 IU of vitamin D_2 per 100 g in the finished food). The labeling requirement in § 172.381(d) ensures that when vitamin D_2 bakers yeast is used to make products, the manufacturer will have the information necessary to use the additive in conformance with the provisions of the regulation.

The second objection from AB Mauri asserts that if FDA is going to approve vitamin D_2 supplementation in baked products at higher levels than are currently permitted by the regulations, it should do so in a way that permits better control of vitamin D levels in finished products by considering the use of vitamin D_3 instead. AB Mauri questions whether vitamin D_2 is as effective for humans as vitamin D_3 at similar levels, and cites two peer-reviewed journal articles to support this claim.

Our evaluation of the petition was based solely on the safety of the proposed use of vitamin D_2 bakers yeast in yeast-containing baked goods. Therefore, expanding the scope of the final rule to provide for the safe use of vitamin D_3 is beyond the scope of the petition submitted by Lallemand. If AB Mauri is interested in obtaining approval for the expanded use of vitamin D_3 in food, they may do so by petitioning FDA for this use in accordance with section 409(b) of the FD&C Act.

IV. Summary and Conclusions

Section 409 of the FD&C Act requires that a food additive be shown to be safe prior to marketing. Under 21 CFR 170.3(i), a food additive is ''safe'' if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the final rule authorizing the use of vitamin D_2 bakers yeast, we concluded that the data presented by the petitioner to establish safety of the additive demonstrate that vitamin D_2 bakers yeast is safe for its intended use in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D_2 per 100 g in the finished food.

The petitioner has the burden to demonstrate the safety of the additive to gain FDA approval. Once we make a finding of safety, the burden shifts to an objector, who must come forward with evidence that calls into question our conclusion (see section 409(f)(1) of the FD&C Act). After evaluating the objections from AB Mauri, we have concluded that the objections do not provide any basis for us to reconsider our decision to issue the final rule authorizing the use of vitamin D_2 bakers yeast as a dual purpose nutrient supplement and leavening agent in yeast-containing baked products at levels not to exceed 400 IU of vitamin D_2 per 100 g in the finished food. Accordingly, we are not making any changes in response to the objections.

Dated: March 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05060 Filed 3–10–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 110 approved new animal drug applications (NADAs) and 14 approved abbreviated new animal drug applications (ANADAs) for new animal drug for use in animal feed from Pfizer, Inc., including its several subsidiaries and divisions, to Zoetis, Inc.

DATES: This rule is effective March 11, 2014.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855; 240–276–8300, *steven.vaughn@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 E. 42d St., New York, NY 10017, and its wholly owned subsidiaries Alpharma, LLC; Fort Dodge Animal Health, Division of Wyeth; Fort Dodge Animal Health, Division of Wyeth Holdings Corp.; and its division, Pharmacia & Upjohn Co., have informed FDA that they have transferred ownership of, and all rights and interest in, the 110 approved NADAs and 14 approved ANADAs in Table 1 to Zoetis, Inc., 333 Portage St., Kalamazoo, MI 4900.

TABLE 1—NADAS AND ANADAS TRANSFERRED FROM PFIZER, INC., TO ZOETIS, INC.

File No.	Product name
007–616	HISTOSTAT 50 (nitarsone) Type A Medicated Article.
011–116	ZOAMIX (zoalene) Type A Medicated Article.
012–375	ALBAMIX (novobiocin) Type A Medicated Article.
012–680	PHARMASTATIN 20 (nystatin) Type A Medicated Article.
013–747	Zoalene 90 Medicated Coccidiostat.
033–950	Sulfamerazine In Fish Grade.
034–085	LINCOMIX (lincomycin) Type A Medicated Article.
034–254	MGA (melengestrol acetate) Type A Medicated Article.
035–688	AUREOMIX Granular 500 (pen G, CTC, sulfamethazine) Type A Medicated Article.
035–805	AUREO S 700 Granular (CTC and sulfamethazine) Type A Medicated Article.
036–361	Amprolium and ethopabate/CTC (chlortetracycline)/sodium sulfate.
039–077	CSP (chlortetracycline, sulfathiazole, and penicillin G procaine) 250 and 500 Type A Medicated Articles.
039–402	MGA 500 (melengestrol acetate) Liquid Type A Medicated Article.
039–417	DECCOX (decoquinate) Type A Medicated Article.
040–209	ROFENAID 40 (sulfadimethoxine and ormetoprim) Type A Medicated Article.
041–647	AUREOMIX S 700–A (CTC and sulfamethazine) Type A Medicated Article.
041–648	AUREOMIX S 700–D (CTC and sulfamethazine) Type A Medicated Article.
041–649	AUREOMIX S 700–G (CTC and sulfamethazine) Type A Medicated Article.