



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<sub>2</sub>

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<sub>2</sub> bakers yeast as a source of vitamin D<sub>2</sub> and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 International Units (IU) of vitamin D<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> bakers yeast as a source of vitamin D<sub>2</sub> and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D<sub>2</sub> 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<sub>2</sub> bakers yeast as a source of vitamin D<sub>2</sub> and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> bakers yeast.

### III. Analysis of Objections

The first objection raised by AB Mauri contends that the regulation authorizing the use of vitamin D<sub>2</sub> bakers yeast in food (§ 172.381) is based on the incorrect assumptions that: (1)

vitamin D<sub>2</sub> bakers yeast can be produced in such a way that the vitamin D<sub>2</sub> levels in the yeast itself can be accurately controlled and declared; and (2) vitamin D<sub>2</sub> bakers yeast can be used by food manufacturers in a way that allows them to control the level of vitamin D<sub>2</sub> 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<sub>2</sub> levels in finished products that exceed the maximum level specified in the regulation and declaration of inaccurate vitamin D<sub>2</sub> levels on finished product nutrition labels.

In support of their claim, AB Mauri presents vitamin D<sub>2</sub> levels from a limited number of samples of Lallemand's commercially available vitamin D<sub>2</sub> 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<sub>2</sub> in bakers yeast varies, and does not necessarily reflect the level of vitamin D<sub>2</sub> that Lallemand claims on its Web site is "typical" for the product. AB Mauri also provides theoretical ranges of vitamin D<sub>2</sub> levels that could result in batches of the same size product, depending on the level and type of vitamin D<sub>2</sub> bakers yeast used. According to AB Mauri, using different levels and types of vitamin D<sub>2</sub> bakers yeast result in different levels of vitamin D<sub>2</sub> in batches of equal size.

However, AB Mauri did not provide the manufacturer's certificates of analysis so that the vitamin D<sub>2</sub> levels of the analyzed samples could be verified. Additionally, AB Mauri did not identify the analytical method used in the analyses of vitamin D<sub>2</sub> 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<sub>2</sub> levels and the vitamin D<sub>2</sub>

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<sub>2</sub> in finished baked products made with vitamin D<sub>2</sub> bakers yeast exceed the maximum permitted level since the levels of vitamin D<sub>2</sub> 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<sub>2</sub> bakers yeast.

Our review of the petition explicitly considered variability of vitamin D<sub>2</sub> in ultraviolet light-treated bakers yeast. The petitioner provided analytical data of vitamin D<sub>2</sub> levels from production lots of vitamin D<sub>2</sub> bakers yeast, including the certificates of analysis for the products analyzed. Results demonstrated that vitamin D<sub>2</sub> levels were at least equal to 80 percent of the value for vitamin D<sub>2</sub> declared on the label of the vitamin D<sub>2</sub> bakers yeast product (see 21 CFR 101.9(g)(4)(ii)). Additionally, certificates of analysis, which include vitamin D<sub>2</sub> levels in the product, are provided with each product sold, thus allowing bakers to calculate the amount of vitamin D<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> contained in the finished food. However, to ensure that the level of vitamin D<sub>2</sub> 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<sub>2</sub> per 100 g in the finished food). The labeling requirement in § 172.381(d) ensures that when vitamin D<sub>2</sub> 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<sub>2</sub> 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<sub>3</sub> instead. AB Mauri questions whether vitamin D<sub>2</sub> is as effective for humans as vitamin D<sub>3</sub> 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<sub>2</sub> bakers yeast in yeast-containing baked goods. Therefore, expanding the scope of the final rule to provide for the safe use of vitamin D<sub>3</sub> 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<sub>3</sub> 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<sub>2</sub> bakers yeast, we concluded that the data presented by the petitioner to establish safety of the additive demonstrate that vitamin D<sub>2</sub> bakers yeast is safe for its intended use in yeast-leavened baked products at levels not to exceed 400 IU of vitamin D<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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.

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