Unilever

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March 31, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02F-0160
Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3
Objections to the Final Rule

To Whom It May Concern:

Pursuant to §409(f) of the Federal Food, Drug, and Cosmetic Act, and 21 CFR 171.110 and 21 CFR Part 12, Unilever United States, Inc. ("Unilever") hereby objects to a final food additive regulation governing the addition of vitamin D_3 to calcium-fortified fruit juices and fruit drinks, 21 CFR 172.380. The final regulation was published at 68 Fed. Reg. 9000 (February 27, 2003), and the deadline for filing objections is March 31, 2003. Unilever is a manufacturer of food products and would be adversely affected by the final regulation as published.

OBJECTIONS

Pursuant to 21 CFR 12.22, the following objections are submitted:

Objection 1: The clause in 21 CFR 172.380(c) which states that "Vitamin D_3 may be added, at levels not to exceed 100 International Units (IU) per serving" is not supported by the administrative record to the extent that it requires the level of added vitamin D_3 to be calculated per serving, rather than per reference amount customarily consumed (RACC). Unilever respectfully requests that this clause be modified to read "Vitamin D_3 may be added, at levels not to exceed 100 International Units (IU) per Reference Amount Customarily Consumed (RACC)".

Objection 2: The clause in 21 CFR 172.380(d) which states that "Vitamin D_3 may be added, at levels not to exceed 100 IU per serving" is not supported by the administrative record to the extent that it requires the level of added vitamin D_3 to be calculated per serving, rather than per RACC. Unilever respectfully requests that this clause be modified to read "Vitamin D_3 may be added, at levels not to exceed 100 IU per RACC".

02F-0160

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GROUNDS FOR THE OBJECTIONS

The basis for each of the two objections stated above is the same, specifically:

> *The requirement that the level of vitamin D_3 be based on serving size, rather than RACC, will result in levels of vitamin D_3 in fortified fruit juices and fruit drinks that are inconsistent, on a per-milliliter basis, with the levels of vitamin D_3 in milk and also with the levels of vitamin D_3 in differently sized containers of fortified fruit juices and fruit drinks. This result would be inconsistent with the intent of the petition that initiated the rulemaking and would also be confusing to consumers.*

These issues are discussed in more detail below.

According to the petition, vitamin D_3 "is intended to be used in calcium-fortified fruit juices and juice drinks at a fortification level *comparable to* that currently approved for vitamin D fortified milk."[1]

The intent of the petition is achieved when the serving size is equivalent to the RACC. Under 21 CFR 184.1950, milk may be fortified with vitamin D at up to 42 IU per 100 grams. Therefore, when milk is labeled with a serving size equal to the RACC (i.e., 240 mL or 8 fl. oz.),[2] it may contain up to approximately 95 IU vitamin D per serving. This would be comparable to the level of vitamin D_3 permitted in calcium-fortified fruit juices and fruit drinks under the new food additive regulation, because the regulation permits up to 100 IU vitamin D_3 per serving.

However, the intent of the petition is not achieved when the serving size is greater than the RACC. For example, if vitamin D-fortified milk is sold in a 12-fl. oz. container and is labeled as a single serving (pursuant to 21 CFR 101.9(b)(6)), then it will contain about 140 IU vitamin D per serving. In contrast, because the new food additive regulation limits vitamin D_3 in calcium-fortified fruit juices and fruit drinks to 100 IU per serving, a 12-fl. oz. container of a vitamin D_3-fortified fruit drink would contain only 100 IU vitamin D_3. This represents a difference in vitamin D_3 content between milk and the fortified fruit drink of almost 30% – a significant difference.

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[1] Petition of the Minute Maid Company, section B.2.2. (February 2002) ("Petition") (emphasis added). We have access only to a version of the petition that has been significantly redacted in the course of being released by FDA under the Freedom of Information Act.

[2] The RACC for all of the beverages referred to in these objections is 240 mL or 8 fl. oz. 21 CFR 101.12(b).

As a result, when vitamin D_3-fortified fruit juices and fruit drinks are sold in single-serving containers that are greater than the RACC of 240 mL (8 fl. oz.), they will contain levels of vitamin D_3 that are not comparable to the levels of vitamin D in milk. Moreover, such products would also be inconsistent, on a per-milliliter basis, with the levels of vitamin D_3 in fortified fruit juices and fruit drinks that are labeled with serving sizes equal to the RACC.

The solution to this problem is to modify the regulatory text to provide for the addition of vitamin D_3 at 100 IU *per RACC* rather than per serving. As a result:

- The permitted levels of vitamin D_3 in fortified fruit juices and fruit drinks would be comparable to the levels in milk, regardless of the labeled serving size, which was the original intent of the petition;

- The permitted levels of vitamin D_3 in fortified fruit juices and fruit drinks would be consistent, on a per-milliliter basis, regardless of the labeled serving size; and

- Consumers would not experience confusion when trying to compare the levels of vitamin D_3 between milk and fortified fruit juices and fruit drinks, and among different serving sizes of fortified fruit juices and fruit drinks.

Finally, we recognize that, in the petition that initiated this rulemaking, the requested regulatory text provided for the addition of vitamin D_3 at 100 IU "per serving." As discussed above, however, the use of "per serving" is inconsistent with the petitioner's stated intent that fruit juices and fruit drinks be fortified at a level comparable to that currently approved for vitamin D-fortified milk. Further, the petitioner expressly stated its intent that fruit juices and fruit drinks be fortified on a "per RACC" basis. The petition stated:

> "Specifically, 100% fruit juice products fortified with ≥33% of the Recommended Dietary Intake (RDI) of calcium per Reference Amount Customarily Consumed (RACC), and juice and juice drinks fortified with ≥10% of the RDI of calcium per RACC, are intended to be fortified with 100 IU (2.5 μg) vitamin D_3 *per RACC*."[3]

Accordingly, based on the petition, FDA is fully justified in modifying the regulatory text to provide for the addition of vitamin D_3 to calcium-fortified fruit juices and fruit drinks at 100 IU per RACC rather than per serving. Such modification would not raise a safety issue because it would simply implement the intent of the petition that vitamin D_3 be

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[3] Petition, section B.2.2 (emphasis added). Indeed, FDA also referred to the addition of vitamin D_3 "per RACC" in the preamble to the regulation. 68 Fed. Reg. 9000.

added to fruit juices and fruit drinks at a level comparable to that for milk. The petition has already established – and FDA has already accepted – the safety of this intended use of vitamin D_3.

CONCLUSION

For the reasons discussed above, Unilever respectfully requests that FDA modify the regulatory text that is the subject of the objections to provide that vitamin D_3 may be added to calcium-fortified fruit juices and fruit drinks at levels not to exceed 100 IU per RACC.

Unilever agrees to withdraw these objections if, in lieu of modifying 21 CFR 172.380 as requested herein, FDA informs us in writing that it will not object to the marketing of calcium-fortified fruit juices and fruit drinks that contain vitamin D_3 at levels not to exceed 100 IU per RACC.

Respectfully submitted,

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Nancy L. Schnell
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