DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 130 and 131

[Docket No. FDA–2000–P–0126 (formerly Docket No. 2000P–0658)]

RIN 0910–AI40

International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of public hearing requests; removal of administrative stay.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) received objections and requests for a hearing from the International Dairy Foods Association (IDFA) and Chobani, Inc. (Chobani) on the final rule titled ''Milk and Cream Products and Yogurt Products; Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt,'' which published on June 11, 2021. The final rule revoked the standards of identity for lowfat yogurt and nonfat yogurt and amended the standard of identity for yogurt in numerous respects. We are denying the requests for a public hearing and modifying the final rule in response to certain objections. Therefore, the stay of the effectiveness for the final regulation is now lifted.

DATES: This rule is effective January 17, 2023. The compliance date of this final rule is January 1, 2024.

ADDRESSES: You may submit objections and request a hearing on new provisions added by this response to objections as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 17, 2023. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2000–P–0126 for ''International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Denial of the Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341) directs the Secretary of Health and Human Services (Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity whenever, in the judgment of the Secretary, such action will promote honesty and fair dealing in the interest of consumers. Under section 701(e)(1) of the FD&C Act (21 U.S.C. 371(e)(1)), any action for the amendment or repeal of any definition and standard of identity under section 401 of the FD&C Act for any dairy product (*e.g.,* yogurt) must begin with a

proposal made either by FDA under our own initiative or by petition of any interested persons.

In the **Federal Register** of June 11, 2021 (86 FR 31117), we issued a final rule amending the definition and standard of identity for yogurt ((§ 131.200) (21 CFR 131.200)) and revoking the definitions and standards of identity for lowfat yogurt (21 CFR 131.203) and nonfat yogurt (21 CFR 131.206). This action was in response, in part, to a citizen petition submitted by the National Yogurt Association (NYA). The final rule modernized the yogurt standard to allow for technological advances while promoting honesty and fair dealing in the interest of consumers.

The preamble to the final rule stated that the effective date of the final rule would be on July 12, 2021, except as to any provisions that may be stayed by the filing of proper objections (86 FR 31117 at 31136). Pursuant to section 701(e) of the FD&C Act, the final rule notified persons who would be adversely affected by the final rule that they could file objections, specifying with particularity the provisions of the final rule deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. We gave interested persons until July 12, 2021, to file objections and request a hearing on the final rule.

The IDFA and Chobani timely filed objections and requested a hearing with respect to several provisions in the final rule (see Objections and Request for Hearings submitted by Michael Dykes, President and Chief Executive Officer, International Dairy Foods Association, dated July 12, 2021, to the Dockets Management Staff, Food and Drug Administration (Comment ID FDA–2000–P–0126–0109) (IDFA objection) and Objection and Requests for Hearing submitted by Matthew Graziose, Director, Regulatory Affairs & Compliance, Chobani, dated July 12, 2021, to the Dockets Management Staff, Food and Drug Administration (Comment ID FDA–2000–P–0126–0108) (Chobani objection)). Section 701(e)(2) of the FD&C Act provides that, until final action is taken by the Secretary, the filing of objections operates to stay the effectiveness of those provisions to which the objections are made.

In the **Federal Register** of March 23, 2022 (87 FR 16394) we issued a notice providing clarification on which provisions of the final rule were stayed and which requirements of the previous final rule that we issued in 1981 (46 FR 9924) are in effect pending final action under section 701(e) of the FD&C Act.

II. Standards for Granting a Hearing

Specific criteria for granting a hearing are set out in § 12.24(b) (21 CFR 12.24(b)). Under that regulation, a hearing will be granted if the material submitted by the requester shows that: (1) there is a genuine and substantial factual issue for resolution at a hearing (a hearing will not be granted on issues of policy or law); (2) the factual issue can be resolved by available and specifically identified reliable evidence (a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions); (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester (a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate); (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested (a hearing will not be granted on factual issues that are not determinative with respect to the action requested, *e.g.,* if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any regulation particularizing statutory standards (the proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved); and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the notice issuing the final regulation or the notice of opportunity for a hearing are met.

A party seeking a hearing must meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any or sufficient factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgement as a matter of law (see *Rule 56, Federal Rules of Civil Procedure*). The same principle applies to administrative proceedings (21 CFR 12.28, see *Vermont Dep't of Pub. Serv.* v. *FERC,* 817 F.2d 127, 140 (D.C. Cir. 1987)).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact ''concerning which a meaningful hearing might be held'' (*Pineapple Growers Ass'n* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982) see also *Cmty. Nutrition Inst.* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, an agency need not grant a hearing (see *Cmty. Nutrition Inst.* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985); *Dyestuffs and Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959)). A hearing is justified only if the objections are made in good faith and if they raise ''material' issues of fact'' (*Pineapple Growers Ass'n,* 673 F.2d at 1085). A hearing need not be held to resolve questions of law and policy (see *Kourouma* v. *FERC,* 723 F.3d 274, 277–78 (D.C. Cir. 2013); *Citizens for Allegan County, Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958)).

Even if the objections raise material issues of fact, we need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality, such as collateral estoppel, can be validly applied to the administrative process (see *Astoria Fed. Sav. & Loan Ass'n* v. *Solimino,* 501 U.S. 104, 107–08 (1991); *Pacific Seafarers, Inc.* v. *Pac. Far East Line, Inc.,* 404 F.2d 804, 809 (D.C. Cir. 1968), *cert. denied,* 393 U.S. 1093 (1969)). In explaining why these principles ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: ''The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity'' (*Retail Clerks Union, Local 1401* v. *NLRB,* 463 F.2d 316, 322 (D.C. Cir. 1972); see also *Costle* v. *Pacific Legal Foundation,* 445 U.S. 198 at 215–17). In addition, under our regulations, we may determine upon review of an objection that the regulation should be modified or revoked (§ 12.26 (21 CFR 12.26)). If the modification or revocation is

consistent with the objector's request, there is no genuine and substantial issue of fact for resolution at a hearing and the hearing may be denied (§ 12.24(b)(1)).

III. Analysis of Objections and Response to Hearing Requests

Under section 701(e) of the FD&C Act and 21 CFR part 12, subpart B, of our regulations, we have considered the objections and requests for a hearing and our conclusions are as follows:

The submission from IDFA contains five numbered objections, and IDFA requests a hearing on each of them. In addition, Chobani submitted one objection and request for a hearing. We address each objection below, as well as the evidence and information filed in support of each. For purposes of clarity, we have maintained the objection numbers assigned by IDFA and Chobani.

IDFA's objections were directed at several provisions in § 131.200(a) of the final rule: (1) the requirement to achieve either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower prior to the addition of bulky flavoring ingredients; (2) those portions of § 131.200(a), (b), and (c) that prohibit the addition of pasteurized cream after culturing; (3) the provision in § 131.200(d)(8)(ii) that would require a yogurt with added vitamin D to contain at least 25 percent Daily Value (DV) vitamin D per Reference Amount Customarily Consumed (RACC); (4) the requirement that yogurt contain not less than 3.25 percent milkfat; and (5) the exclusion of safe and suitable ''non-nutritive sweeteners'' from paragraph (d)(2) as an optional ingredient and the limitation of their use to only those instances where the product bears an expressed nutrient content claim as part of the product name, such as ''reduced calorie yogurt'' or ''reduced sugar yogurt,'' under § 130.10 (21 CFR 130.10).

In addition, Chobani objected to the provision in § 131.200(b) as it does not allow for ultrafiltered milk to be used as a basic dairy ingredient, and Chobani requested a hearing.

A. IDFA Titratable Acidity and pH Objections

In this objection, IDFA asserted that the final rule's requirement that yogurt has either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower before the addition of bulky flavoring ingredients (such as fruits and fruit preparations), is not practical and does not reflect consumer taste preferences or current industry practice for yogurt manufacturing. IDFA stated that the requirement will not promote honesty and fair dealing in the interest of consumers. IDFA asserted that the requirement should be a titratable acidity of not less than 0.6 percent, expressed as lactic acid, measured in the white mass of the yogurt, or a pH of 4.6 or lower measured in the finished product within 24 hours after filling. IDFA requested a hearing on the following issues: (1) whether a requirement that titratable acidity or pH be reached prior to the addition of bulky flavors in the manufacturing process is consistent with the basic nature and essential characteristics of yogurt; (2) whether a requirement that prohibits yogurt from being filled at a pH of 4.8 or less and reaching a pH of 4.6 or below within 24 hours after filling is consistent with the basic nature and essential characteristics of yogurt; and (3) whether a minimum titratable acidity requirement of 0.7 percent is in the interest of consumers and necessary to maintaining the basic nature and essential characteristics of yogurt.

We have addressed this objection and request for a hearing in a letter and proposed order sent to IDFA pursuant to § 12.24(d). We are issuing the proposed order to deny IDFA's request for a hearing with respect to pH pursuant to § 12.24(b)(1), and also deny the request for a hearing with respect to titratable acidity pursuant to § 12.24(b)(1). A copy of the proposed order is available in Docket No. FDA–2000–P–0126 (formerly Docket No. 2000P–0658). (See instructions for accessing the docket.)

B. IDFA Objection to the Requirement That Cream Be Added Before Culturing

IDFA objected to § 131.200(a), (b), and (c) insofar as they prohibit the addition of pasteurized cream after culturing and asked FDA to stay such provisions. The final rule under § 131.200(a) requires that pasteurized cream, if used as a basic dairy ingredient under § 131.200(b) or an optional dairy ingredient under § 131.200(c), be added before culturing with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus.* IDFA requested that we revise the final rule to allow for pasteurized cream to be added after culturing.

IDFA contended that the addition of pasteurized cream after culturing is consistent with the basic nature and essential characteristics of yogurt and requested a hearing on this issue. IDFA explained that ''milkfat is not critical to the basic nature and properties of yogurt, in large part because the yogurt cultures do not act on the milkfat during the culturing process, so the addition of a milk-derived ingredient like cream after culturing does not alter the key characteristics of the product'' (IDFA objection at page 6). Even if milkfat is not acted upon during the culturing process, it does not follow that any milk-derived ingredient will not be acted upon during the culturing process and therefore will not change the characteristics of the end product depending on whether it is added before or after culturing. IDFA's argument appears to be based on the assumption that cream is comprised entirely of milkfat. We note that IDFA did not provide any evidence in its objection that cream is comprised entirely of milkfat and that other components are not present.

In fact, cream is comprised of several components other than milkfat. These components include lactose and protein (Refs. 1 to 3). Under 21 CFR 131.3(a), cream used in the manufacture of yogurt is only required to have a minimum of 18 percent milkfat. While the milkfat content of cream above this minimum may vary, lactose and protein are still present. For example, heavy whipping cream has been reported to have fat content of 36.8 percent, lactose content of 3.2 percent, and protein content of 2.2 percent (see Ref. 1). Whole milk—which IDFA does not dispute should be included in culturing (IDFA objection page 6)—has been reported to have fat content of 3.8 percent, lactose content of 4.9 percent, and protein content of 3.2 percent. While the milkfat content of these two dairy ingredients is very different, the lactose content and protein content are similar. The lactose in cream can be fermented and impact the characteristics of the end product (Ref. 3), as is the case in the production of sour cream (see 21 CFR 131.160(a)).

IDFA acknowledges that lactose and protein are subject to action by yogurt cultures during fermentation and impact the characteristics of yogurt. IDFA states, on page 6 of its objection, that ''addition of milk and milk-derived ingredients that contain significant amounts of lactose, proteins and amino acid peptides, which are indeed subjected to action by yogurt cultures during fermentation, do play a role in providing the unique organoleptic characteristics of yogurt.'' IDFA further states, on page 7, that ''the main contribution to the unique flavor and aroma of plain, unflavored yogurt derives from the homofermentative metabolism of lactose in the milk and the lactose-containing milk-derived ingredients by the two defining thermophilic (or more accurately, ''thermotolerant'') yogurt cultures *L.*

bulgaricus and *S. thermophilus*.'' Thus, by IDFA's own admission, the characteristics of yogurt are impacted by whether components of cream are added before or after culturing.

Since 1981, cream has not been permitted to be added after culturing in the manufacture of yogurt. None of the evidence provided by IDFA specifically examines the addition of cream after culturing in the manufacture of yogurt and compares the end product to yogurt manufactured with cream added before culturing. To justify a change in the production of yogurt from how it has been produced for 40 years, IDFA would have needed to provide evidence that the addition of cream—not merely the addition of milkfat—does not impact the characteristics of yogurt from how it has been produced and sold to consumers. The publications cited by IDFA (Refs. 4 to 7) do not address impacts on the characteristics of yogurt from the use of cream, and more specifically from the use of cream after culturing. Moreover, the expert witness testimony described in appendix 8 of IDFA's objection is specifically about the addition of milkfat to yogurt and not about the addition of cream to yogurt. We conclude that the data and information submitted, if established at a hearing, would not be adequate to justify resolution of the factual issue in the way sought by IDFA. The data and information submitted are insufficient to justify the factual determination urged, even if accurate. Therefore, under § 12.24(b)(3), we deny IDFA's request for a hearing on whether the addition of pasteurized cream after culturing is consistent with the basic nature and essential characteristics of yogurt.

Additionally, IDFA did not provide evidence to support its assertion that the addition of pasteurized cream after culturing does not affect the texture of yogurt. We are denying IDFA's request for a hearing with respect to this issue as it based on mere allegations or denials and not on any available and specifically identified reliable evidence (see § 12.24(b)(2)). We note that evidence (Ref. 8) gathered by FDA indicates that adding cream before culturing increases the yogurt's viscosity and firmness, and decreases the serum separation, contributing to the characteristic texture of yogurt. When cream is added after culturing, the fat globules do not serve a structure-building function but are only present in the structure as a filling substance (Refs. 8 and 9). The force that would be necessary to blend pasteurized cream homogeneously through the yogurt if it were added after culturing, as well as the additional moisture present in pasteurized cream, could affect the texture of the yogurt. Thus, given the absence of evidence to support IDFA's contention and available evidence to the contrary, the data and information submitted are inadequate to justify the resolution of the factual issue in the way sought by IDFA (see § 12.24(b)(3)).

We further note that adequacy of either factual issue (*i.e.,* impact of addition of cream after culturing on taste, aroma, and flavor and impact of addition of cream after culturing on texture) is not sufficient to justify amending the standard of identity to permit the addition of cream after culturing. Both factual issues must be resolved in the way sought by IDFA to justify such an amendment. Accordingly, we also deny IDFA's request for a hearing under § 12.24(b)(4).

IDFA stated that allowing the addition of pasteurized cream after culturing improves production efficiency and reduces manufacturing costs. While we recognize the importance of these issues for yogurt manufacturers, impacts on production efficiency and manufacturing costs do not present genuine and substantial issues of fact as they are not material to whether a food standard promotes honesty and fair dealing in the interest of consumers—which is the basis under the law for establishing food standards (21 U.S.C. 341). Historically, we have determined the requirements of food standards issued under section 401 of the FD&C Act based on whether the requirements would prevent economic adulteration, maintain the integrity of food (*i.e.,* basic nature and essential characteristics), or ensure that products meet consumer expectations about the food.

We note that interested parties can submit a Temporary Marketing Permit (TMP) application in accordance with 21 CFR 130.17 for the addition of pasteurized cream after culturing in yogurt and lower fat yogurt. As discussed above, given FDA regulations have required since 1981 that cream be added before and not after culturing when used in the manufacture of yogurt, a TMP would allow parties to gather appropriate supporting data to support that the addition of cream after culturing is consistent with the basic nature and essential characteristics of yogurt and lower fat yogurt.

C. IDFA Objection to the Optional Addition of Vitamin D

IDFA objected to the provision in § 131.200(d)(8)(ii), which requires that, if added, vitamin D must be present in such quantity that the food contains not less than 25 percent DV per RACC within limits of current good manufacturing practices. IDFA requested that the provision be modified to lower the minimum added vitamin D level to 10 percent DV per RACC. Alternatively, IDFA requested a hearing on the amount of vitamin D in yogurt that would be consistent with consumer expectations and the basic nature and characteristics of yogurt that contains added vitamin D, and aligned with current regulatory limitations.

In support of its proposed modification, IDFA asserted that a minimum vitamin D threshold of 25 percent DV per RACC conflicts with the level authorized by our generally recognized as safe (GRAS) regulation for vitamin D, which sets the limit for vitamin D in milk products at 89 International Units (IU) per 100 grams (g) of food (21 CFR 184.1950(c)(1)), equivalent to 3.8 micrograms (mcg) per RACC. In addition, IDFA asserted that the required level of vitamin D provided for in the final rule is unreasonably high in light of the basic nature of yogurt and does not promote the interests of consumers.

We acknowledge that, under the minimum vitamin D threshold in the final rule, yogurt with added vitamin D must contain at least 5 mcg per RACC and therefore would be above the maximum threshold of 3.8 mcg per RACC permitted under our GRAS regulation. This effectively prevents manufacturers from fortifying their yogurt products with vitamin D and is not what we intended under the final rule. We note that vitamin D is identified as a nutrient of public health concern under the *Dietary Guidelines for Americans, 2020–2025.*

We agree with IDFA's proposal to modify § 131.200(d)(8)(ii) to set a minimum level of vitamin D at 10 percent DV per RACC. This level equates to a minimum of 2 mcg per RACC. Thus, there would be a range of 2 to 3.8 mcg per RACC within which manufacturers could comply with the GRAS regulation and also optionally fortify yogurt with vitamin D under the yogurt standard of identity. A minimum amount of 2 mcg per RACC is the minimum amount at which the Agency deems a food to be a ''good source'' of vitamin D (see our nutrient content claim regulation under 21 CFR 101.54(c)(1)). The minimum in § 131.200(d)(8)(ii) applies to nonfat yogurt, lowfat yogurt, and reduced fat yogurt under § 130.10. Consequently, yogurt and lower fat yogurt products containing added vitamin D under the modified final rule will continue to be a good source of vitamin D for consumers.

We note that a minimum of 10 percent DV per RACC, or 2 mcg per RACC, is similar to the minimum under the standard of identity before it was amended in 2021 by the final rule. From 1982 to 2021, vitamin D addition to yogurt was permitted at a level of 400 IU per quart (see 47 FR 41519 at 41520 and 41524, September 21, 1982). This amount equates to approximately 1.74 mcg per RACC. Thus, modifying the standard of identity to require a minimum vitamin D level of 10 percent DV per RACC, results in a similar amount of vitamin D as was previously permitted under the standard and does not alter the characteristics of yogurt with respect to fortification with this nutrient.

We find that our own analysis and the information provided by IDFA in their objection present sufficient grounds for amending the standard of identity under § 131.200(d)(8)(ii) such that yogurt is required to contain at least 10 percent DV per RACC of vitamin D, within limits of current good manufacturing practices, when vitamin D is added. This amendment is consistent with IDFA's proposed modification. Therefore, we are denying IDFA's request for a hearing regarding the amount of vitamin D in yogurt because there is not a genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1)).

D. IDFA Objection to the 3.25 Percent Minimum Milkfat Requirement

IDFA also objected to the requirement in § 131.200(a) that yogurt contain not less than 3.25 percent milkfat. IDFA asserted that the 3.25 percent minimum milkfat requirement is not consistent with the basic nature and essential characteristics of yogurt, nor does it reflect current industry practices. IDFA further asserted that the requirement creates naming anomalies and restricts innovation and the use of flavoring ingredients. IDFA requested that we modify the final rule to include a minimum total fat content of >3.0 g per RACC instead of the 3.25 percent milkfat minimum (5.5 g per RACC). IDFA requested a hearing on whether ''(1) a 3.25 percent milkfat minimum is critical to the basic nature and characteristics of yogurt; and (2) whether fat/oils from nondairy ingredients, particularly flavoring ingredients, could contribute to variances in the taste, texture, color, or aroma of yogurt and is inconsistent with the basic nature and essential characteristics of the food'' (IDFA objection at page 15).

In support of its contention that milkfat does not contribute to the basic nature and essential characteristics of yogurt and that no minimum milkfat requirement is needed, IDFA relied on the discussion in its second objection (*i.e.,* the requirement that cream be added before culturing). IDFA stated that if a hearing were granted, it would provide evidence ''demonstrating that milkfat is not critical to the basic nature and characteristics of yogurt, in large part because the yogurt cultures do not act on the milkfat during the culturing process'' (*Id.*). IDFA further stated that it would present ''testimony by experts in yogurt production and presentation of scientific publications by subject matter experts demonstrating the results of sensory and analytical chemistry research conducted that has identified the specific compounds that contribute most to the unique flavors and aromas of yogurt and how they are derived predominantly through lactose fermentation'' (*Id.*).

The discussion in IDFA's second objection is about whether milkfat is fermented and whether the end product is impacted by the addition of milkfat after culturing rather than before culturing. The second objection does not address whether a reduction of milkfat in the end product changes the characteristics of yogurt. The evidence described by IDFA similarly focuses on whether milkfat is acted upon during the culturing process and not on whether the absence of milkfat from the end product affects the basic nature and essential characteristics of yogurt. Even if it is true that components other than milkfat contribute most to the flavor and aroma of yogurt, this does not preclude the possibility that milkfat also contributes to the flavor and aroma or other essential characteristics of yogurt. In this objection, the issue is whether a reduction of milkfat from the 3.25 percent minimum in the end product affects the basic nature and essential characteristics of yogurt, not whether milkfat is acted upon during culturing or whether other components affect the essential characteristics of yogurt.

The publications cited by IDFA do not support that a reduction in milkfat in the end product does not affect the basic nature and essential characteristics of yogurt. References 5, 6, and 7 speak solely to the metabolic activity of the fermentation organisms on the components of the yogurt base (carbohydrates, proteins, lipids). The impact of the microorganisms on the fat component appears to be measurable (see Ref. 7, Table 7.11 on Page 578) but potentially minimal in comparison to other components produced by the fermentation of lactose. The publications do not address the physical presence of fat on the characteristics of the end product. Routray and Mishra (Ref. 4) review the influence of fat content on the persistence of volatile flavor compounds, the distribution of flavor compounds throughout the yogurt matrix, and the necessity of fat replacers to achieve similar texture and flavor release. Additionally, they discuss the importance of fat as a structuring material in yogurt.

Moreover, statements made by IDFA in its objection support that milkfat contributes to the basic nature and essential characteristics of yogurt. In its second objection, IDFA states, ''milkfat has an impact on the organoleptic characteristics of yogurt regardless of whether added before or after fermentation'' (*Id.* at page 7). In this objection IDFA asserts, ''yogurt made with milkfat indeed has volatile fatty acids and other compounds that contribute to flavor and aroma'' (*Id.* at page 12) and ''milkfat does not need to be present in the fermented dairy ingredients to contribute to the basic and essential characteristics of yogurt'' (*Id.* at page 13). Thus, by IDFA's own admissions, milkfat contributes to the characteristics of yogurt.

IDFA made additional arguments about consumer preferences for lower fat yogurt products and the absence of a milkfat requirement from the Codex Standard for Fermented Milks. The claim that most consumers prefer lower fat yogurt products to yogurt does not address the issues of whether consumers who purchase yogurt, rather than lower fat yogurt, expect it to contain milkfat or whether the 3.25 percent minimum milkfat requirement ensures that yogurt has the characteristics consumers expect and that distinguish it from lower fat yogurt. Even if most consumers prefer lower fat yogurt products, the 3.25 percent minimum milkfat requirement does not prohibit the marketing of these products when labeled with their respective nutrient content claims. Evidence demonstrating that total fat is of greater significance to consumers than milkfat also would not address these issues. Regarding the absence of a milkfat minimum from the Codex standard, the Codex standard is an international standard and does not reflect yogurt products sold in the United States or American consumers' expectations about yogurt.

Since the yogurt and lowfat yogurt standards of identity were established in 1981, yogurt and lowfat yogurt sold in the United States have been required to have a minimum of 3.25 percent and 0.5 to 2 percent milkfat, respectively. Reduced fat yogurt has been required to

have milkfat content between the minimum for yogurt and the maximum for lowfat yogurt since the 1990s when the general definition and standard of identity under § 130.10 was established (see 58 FR 2431 at 2446, January 6, 1993). Thus, for 40 years, consumers have been accustomed to yogurt and lowfat yogurt containing milkfat; and for nearly 30 years, consumers have been accustomed to reduced fat yogurt containing milkfat. A review by FDA of products on the market sold as ''yogurt'' found that the vast majority contain at least 3.25 percent milkfat (Ref. 10). IDFA has not presented information that these products would retain the characteristics consumers expect and that distinguish the foods if they were changed to contain no milkfat or less milkfat than the amount required.

Because the data and information submitted by IDFA are insufficient to justify that a reduction of milkfat from the 3.25 percent minimum does not affect the basic nature and essential characteristics of yogurt, we deny IDFA's request for a hearing on whether the 3.25 percent milkfat minimum is critical to the basic nature and essential characteristics of yogurt under § 12.24(b)(3).

IDFA also requested a hearing on whether fat or oils from nondairy ingredients, particularly flavoring ingredients, could contribute to variances in the taste, texture, color, or aroma of yogurt and is inconsistent with the basic nature and essential characteristics of the food. In the preamble to the final rule, we explained that nondairy fats or oils can contribute to variances in the taste, texture, color, or aroma of yogurt if they replace the milkfat in yogurt (86 FR 31117 at 31121). IDFA responded in its objection that non-dairy fats and oils are not part of the allowed optional ingredients and that, if a fat source is not part of a flavoring ingredient (*e.g.,* coconut flakes, cacao), it may not be added. We agree with this interpretation and therefore interpret IDFA's request for a hearing to pertain to whether the addition of non-milkfat from flavoring ingredients is inconsistent with the basic nature and essential characteristics of yogurt and lower fat yogurt.

To the extent that the request pertains to the addition of non-milkfat from flavoring ingredients in addition to the milkfat required for yogurt under § 131.200 and lower fat yogurt under § 130.10, we agree that addition of non-milkfat from flavoring ingredients should be permitted and is consistent with the basic nature and essential characteristics. The final rule permits the addition of flavoring ingredients, including fat-containing flavoring ingredients under § 131.200(d)(3). However, as explained in IDFA's objection, the final rule does not permit the addition of fat-containing flavoring ingredients to lower fat yogurt under § 130.10 since the nutrient content claims for ''nonfat,'' ''lowfat,'' and ''reduced fat'' limit the amount of fat that products may contain and the limit has already been met by milkfat. IDFA explained that lowerfat yogurt products are consequently precluded from containing flavoring ingredients such as coconut and cacao.

We agree that this limitation may restrict innovation and prevent the manufacture and sale of lowerfat yogurt products that consumers expect. Accordingly, we are modifying § 130.10 to add new paragraph (e) to permit fat-containing flavoring ingredients in nonfat yogurt, lowfat yogurt, and reduced fat yogurt. These products are still required under § 130.10 (a) to contain milkfat in the amount corresponding to the nutrient content claims in their names; however, the modified rule permits fat from flavoring sources to be added above the fat content of the nutrient content claim. Such products must be labeled with the nutrient content claim corresponding to their milkfat content and a descriptor of the flavoring ingredient (*e.g.,* ''lowfat yogurt with cashews''). The descriptor should describe in plain language the identity of the flavoring ingredient (*e.g.,* cashews, chocolate chips, coconut).

We are also modifying the final rule to permit yogurt with milkfat content between the upper limit for reduced fat yogurt (2.44 percent) and the minimum requirement for yogurt (3.25 percent). New paragraph (g) under § 131.200 specifies that yogurt may contain less than 3.25 percent milkfat but at least 2.44 percent milkfat and that such products must be labeled with a statement of the milkfat percentage rounded to the nearest half percent (*e.g.,* ''2.5 percent milkfat''). Under § 131.200(d)(3), such products are permitted to contain flavoring ingredients that increase the total fat content. These modifications to § 131.200 address the gap in milkfat allowance identified by IDFA in its objection (IDFA objection at pages 13–14) and allow the manufacture and sale of yogurt products with milkfat not previously covered by the final rule or the 1981 final rule.

As a consequence of our modifications to § 130.10 and § 131.200, manufacturers may produce yogurt products with any amount of milkfat within the specified limits and with additional fat content from flavoring ingredients. This introduces flexibility into the standards of identity and provides new opportunities for innovation as requested by IDFA. An amendment to replace the 3.25 percent minimum milkfat requirement with >3.0 grams of fat per RACC requirement is not needed to accomplish these purposes. The modified final rule also allows manufacturers to produce yogurt products with less saturated fat, consistent with recommendations in the *Dietary Guidelines for Americans 2020–2025,* since the total fat content can exceed the limit for the nutrient content claim and milkfat need not be increased to 3.25 percent. Yogurt products will continue to be named according to the milkfat limits in the final rule (*i.e.,* ''yogurt,'' ''reduced fat yogurt,'' ''lowfat yogurt,'' and ''nonfat yogurt''). These names have been in place for decades and have distinguished yogurt products from each other and are recognized by consumers. While the ingredient statement may indicate that dairy ingredients are present, it does not explicitly inform consumers that milkfat is present or in what quantity. Because we agree with IDFA that non-milkfat from flavoring ingredients should be permitted in yogurt and lower fat yogurt above the minimum milkfat requirements and have modified the final rule accordingly, IDFA's request for a hearing is denied under § 12.24(b)(1) as there is no genuine and substantial issue of fact for resolution at a hearing.

To the extent that IDFA's request for a hearing pertains to the addition of non-milkfat from flavoring ingredients as a replacement for milkfat in yogurt and lower fat yogurt, we deny IDFA's request for a hearing under § 12.24(b)(3) because the data and information submitted are insufficient to justify that use of fat and oils from nondairy flavoring ingredients to replace milkfat in yogurt is consistent with the basic nature and essential characteristics of yogurt. First, as explained above, IDFA has not submitted information sufficient to justify that a reduction in milkfat does not affect the basic nature and essential characteristics of yogurt. IDFA also has not presented evidence that consumers who purchase lower fat yogurt products (other than nonfat yogurt) do not expect them to contain milkfat or that their lower milkfat levels do not contribute to their characteristics. Second, IDFA stated in its objection that it would present examples and sales volumes demonstrating that fat from nondairy ingredients is consistent with the basic

nature and essential characteristics of many flavored yogurts on the market today and accepted by consumers. It is unclear what examples IDFA would present and whether such examples would be representative of the market. It is also unclear what is meant by ''sales volumes'' and how sales of certain products would demonstrate consumer acceptance. Nevertheless, yogurt, lowfat yogurt, and nonfat yogurt prior to and after publication of the final rule have been required to contain certain milkfat content. Thus, examples and sales of products on the market would not pertain to products that contain fat or oils from non-dairy flavoring ingredients as a replacement for milkfat and would not be sufficient to justify the factual determination urged by IDFA.

E. IDFA Objection to the Exclusion of Safe and Suitable Non-Nutritive Sweeteners

IDFA objected to the exclusion of safe and suitable ''non-nutritive sweeteners'' from § 131.200(d)(2) as an optional ingredient and to the limitation of the use of non-nutritive sweeteners to products bearing a nutrient content claim as part of the name or statement of identity. IDFA asserted that ''[t]he use of non-nutritive sweeteners is consistent with the basic nature of a sweetened yogurt'' (IDFA objection at page 16) and requested a hearing on ''whether the use of safe and suitable non-nutritive sweeteners is consistent with the basic nature or essential characteristics of sweetened 'yogurt' '' (*Id.* at page 20). IDFA requested that we modify § 131.200(d)(2) to replace ''nutritive carbohydrate sweeteners'' with ''sweeteners,'' thereby permitting both nutritive and non-nutritive sweeteners in the manufacture of yogurt (*Id.*).

In support of its contention that the use of non-nutritive sweeteners is consistent with the basic nature and essential characteristics of yogurt, IDFA referenced our conclusion in the 2009 proposed rule that yogurt could be sweetened with non-nutritive sweeteners ''without adversely affecting the basic nature and essential characteristics of yogurt'' (*Id.*). IDFA also pointed to our enforcement discretion policy since 2009 (74 FR 2443 at 2455) regarding the use of non-nutritive sweeteners in yogurt labeled without a nutrient content claim, such as ''reduced calorie,'' as part of the name of the food. IDFA explained that yogurt products containing non-nutritive sweeteners without a nutrient content claim as part of the name of the food have been sold during this period of enforcement discretion and are commonly found on the market today.

Our rationale in the final rule for permitting the use of non-nutritive sweeteners only when making a nutrient content claim was to be consistent with the intention of the regulatory framework of § 130.10 after the Nutritional Labeling and Education Act (NLEA). We explained in the final rule that non-nutritive sweeteners should only be permitted when making a nutrient content claim and therefore when the product is subject to the general definition and standard of identity in § 130.10 (86 FR 31117 at 31128). We believed that this approach would address the comments we received to the proposed rule (74 FR 2443) concerning the presence and disclosure of artificial sweeteners while also providing manufacturers flexibility to make modified yogurt products with non-nutritive sweeteners.

Upon consideration of IDFA's objection, we agree that non-nutritive sweeteners should be permitted in yogurt without being labeled with a nutrient content claim. We acknowledge that, since the publication of the proposed rule, we have exercised enforcement discretion for yogurt products containing non-nutritive sweeteners as an optional ingredient and that do not bear a nutrient content claim as part of the statement of identity. During this 12-year period, we did not encounter any consumer issues or receive information that the use of non-nutritive sweeteners was inconsistent with what consumers expect or that such use adversely impacted the characteristics of the food. Disclosure of non-nutritive sweeteners in the ingredient statement appears to have been adequate to notify consumers of their presence. We note that non-nutritive sweeteners are declared by their common or usual names and therefore their presence is explicitly stated. We further note that nutrient content claims such as ''reduced calorie'' or ''reduced sugar'' do not necessarily inform consumers that non-nutritive sweeteners are present and may indicate that other modifications to the food have been made (*e.g.,* a ''reduced calorie'' nutrient content claim could also be met by reducing fat or lactose). In light of this information, we conclude that the use of non-nutritive sweeteners in yogurt products that do not bear a nutrient content claim is consistent with the basic nature and essential characteristics of yogurt and promotes honesty and fair dealing in the interest of consumers.

Upon further consideration, we find the limitation on non-nutritive sweeteners to only those products labeled with nutrient content claims to be inconsistent with our public health goals and policies. The *Dietary Guidelines for Americans 2020–2025* encourage consumers to limit their intake of added sugar. The sugar content of food, including yogurt, is often reduced by replacing sugar with non-nutritive sweeteners. Thus, the use of non-nutritive sweeteners in yogurt may help reduce added sugar intake. Although non-nutritive sweeteners are currently permitted in products with a nutrient content claim, such as ''reduced calorie'' or ''reduced sugar,'' the products must achieve a level of sugar reduction, *e.g.,* 25 percent less calories or sugar, to qualify for the nutrient content claim (see § 101.60). Thus, if sugar reduction falls below this threshold (*e.g.,* 25 percent less calories or sugar), then the products are not permitted to contain non-nutritive sweeteners. We seek to encourage sugar reduction even at lower levels as cumulatively these changes can make a difference in public health. Permitting non-nutritive sweeteners in yogurt is also consistent with our public health goals and policies, which seek to improve nutrition and encourage the development of more healthful foods.

For the reasons explained above, we are modifying § 131.200(d)(2) to permit ''sweeteners'' as optional ingredients in yogurt, consistent with IDFA's request. Accordingly, IDFA's request for a hearing is denied under § 12.24(b)(1) as there is no genuine and substantial issue of fact for resolution at a hearing.

F. Chobani Objections Regarding Ultrafiltered Milk

Chobani requested we permit the use of ultrafiltered (UF) milk as a basic dairy ingredient in yogurt. They objected to § 131.200(b) because it does not include UF milk as a basic dairy ingredient and therefore § 131.200(a) does not permit UF milk as a basic dairy ingredient in yogurt. Chobani provided several reasons for objecting to the exclusion of UF milk from § 131.200(b). We interpret these reasons as follows: (1) the use of UF milk as a basic dairy ingredient is consistent with the basic nature and essential characteristics of yogurt; (2) the use of UF milk as a basic dairy ingredient is safe; (3) the use of UF milk as a basic dairy ingredient will result in products with health benefits and that are as nutritious or more nutritious than yogurt produced without UF milk; (4) use of UF milk as a basic dairy ingredient will improve the efficiency of yogurt-making; (5) permitting use of UF milk would be consistent with other dairy standards of identity; and (6)

permitting the use of UF milk would be consistent with international standards for yogurt. Despite these various reasons, Chobani requested a hearing on only two issues: (1) the minimum lactose content as a substrate for bacterial cultures to develop the characteristics of ''yogurt;'' and (2) nutritional comparisons of products made from UF milk to that of traditional ''yogurt'' and other dairy foods.

Related to its first request for a hearing, Chobani stated, ''ultrafiltered milks can be used as the basic ingredient in yogurt making, with additional dairy ingredients added to reach a level of lactose that can be fermented to reach the titratable acidity/pH requirements for yogurt and result in the minimum level of characterizing bacterial cultures (*Lactobacillus delbrueckii* ssp. *Bulgaricus* and *Streptococcus thermophilus*) as specified by the standard'' (Chobani objection at page 2). Chobani did not cite any evidence to support this contention. Furthermore, while the acidity of yogurt and characterizing bacterial culture content are important characteristics of yogurt, they are not the only essential characteristics of yogurt that should be maintained by the use of UF milk. The organoleptic characteristics and texture of yogurt should also be maintained. Chobani's objection referred to sensory quality, but did not provide any evidence to support that the sensory quality of yogurt is unaffected by the lactose content of UF milk or by the use of UF milk more generally. In sum, Chobani did not provide any evidence of the minimum lactose content, whether from UF milk or UF milk and other basic dairy ingredients combined, that would be necessary to maintain the characteristics of yogurt. We deny Chobani's first request for a hearing under § 12.24(b)(2) because the material submitted by Chobani does not show that this factual issue can be resolved by available and specifically identified reliable evidence.

Chobani did not present any information on the lactose content of UF milk that would be used as a basic dairy ingredient in yogurt making. As we noted in the final rule, fluid UF milk and its dried products are distinctly different from milk and dried milk, respectively (86 FR 31117 at 31125). The process of ultrafiltration selectively removes not only water, but also lactose, minerals, and water-soluble vitamins, resulting in a compositionally different ingredient (86 FR 31117 at 31125). Depending on the pore size of the membrane(s) used, ultrafiltration can be used to process milk to concentrate casein and whey proteins and to partially remove lactose and water-soluble minerals and vitamins. Milk may be UF until a desired protein concentration is reached and, depending on the processing conditions (*e.g.,* use of diafiltration), can result in removal of the majority of lactose and water-soluble minerals and vitamins. The amount of lactose is commonly and significantly reduced in UF milk (Ref. 11). We understand from this information that the final composition of UF milk, including the lactose content, can vary significantly and we cannot infer a certain composition and lactose content in UF milk in yogurt making. Thus, even if Chobani presented evidence of the minimum lactose content necessary to maintain the characteristics of yogurt, Chobani has not provided evidence that UF milk used in yogurt making would contain this level and therefore maintain the characteristics of yogurt. We deny Chobani's first request for a hearing under § 12.24(b)(4) because resolution of the factual issue in the way sought by Chobani is not adequate to justify amending the final rule to permit UF milk as a basic dairy ingredient.

UF milk has many constituents, only one of which is lactose. The other constituents—protein, minerals, vitamins, and water—vary in UF milk and are different than the levels in milk. Differences in these constituents may affect the basic nature and essential characteristics of yogurt when UF milk is used as a basic dairy ingredient in the manufacture of yogurt. Chobani has not provided any evidence that these differences will not change the basic nature and essential characteristics of yogurt. As such, we further deny Chobani's first request for a hearing under § 12.24(b)(4). Even if Chobani provided evidence sufficient to justify that the lactose content of UF milk that would be used in yogurt-making maintains the characteristics of yogurt, Chobani has not shown that the content of other components in UF milk used in yogurt making do not impact the basic nature and essential characteristics of yogurt.

To the extent the studies cited in references 1 and 2 of Chobani's objection (Refs. 12 and 13) are intended to support its first request for a hearing, we deny the request for a hearing under § 12.24(b)(3). Neither publication quantifies the amount of lactose necessary to produce products with the characteristics of yogurt. The publication by Uduwerella showed that it was possible to use UF milk to produce products with a pH less than 4.6 (without the addition of lactose), but stated that the physical characteristics (texture) of the yogurt were different than yogurt produced without UF milk. In the publication by Valencia, the use of UF milk resulted in a product with a higher pH than the maximum pH in the standard of identity (*i.e.,* pH of 4.6). We note also that the publications were limited in the characteristics of yogurt examined. The publication by Uduwerella did not examine the impact of UF milk on taste, and the publication by Valencia did not examine the impact of UF milk on taste or texture. Both publications were about the manufacture of Greek-style yogurt rather than the manufacture of yogurt in general. We conclude that these referenced articles are not adequate to determine the minimum lactose content to manufacture products with the characteristics of yogurt. They also are not adequate to determine whether UF milk used in yogurt making would have sufficient lactose or would otherwise be sufficient for use as a basic dairy ingredient such that products would have the characteristics of yogurt.

Chobani also requested a hearing on ''nutritional comparisons of products made from UF milk to that of traditional 'yogurt' and other foods in the Dairy group'' (*Id.*). We interpret ''traditional 'yogurt' '' to mean yogurt that is produced without UF milk as a basic dairy ingredient. Chobani explained in its objection that ''Products made from ultra-filtered milks can deliver the same type and amounts of essential vitamins and minerals that consumers have come to expect from yogurts—including a good source of calcium, a good source of phosphorous, excellent source of vitamin B12 and an excellent source of protein'' (*Id.*). Chobani further explained that ''Yogurts made from ultrafiltered milk can deliver levels of magnesium and potassium which are consistent with other foods which count towards Americans overall consumption of dairy for the purposes of dietary monitoring and guidelines development'' (*Id.*). Chobani did not provide any evidence of the nutrient content of UF milk and therefore has not shown that the nutritional comparisons can be made by available and specifically identified reliable evidence (§ 12.24(b)(2)).

Even if we assume the truth of Chobani's statements (*i.e.,* that yogurt made with UF milk as a basic dairy ingredient has the same or better level of nutrients than yogurt made without UF milk as a basic dairy ingredient or has similar levels of nutrients as other dairy foods), such finding would not be a sufficient basis for modifying the final rule to permit UF milk as a basic dairy ingredient in yogurt. Chobani must

demonstrate that the use of UF milk as a basic dairy ingredient is consistent with the basic nature and essential characteristics of yogurt. If we assume that some or all of these nutrients contribute to the basic nature and essential characteristics of yogurt, the other essential characteristics of yogurt (*e.g.,* taste and texture) must nevertheless be addressed. Hence, we also deny Chobani's second request for a hearing under § 12.24(b)(4) because resolution of the factual issue in the way sought by Chobani would not be adequate to justify amending § 131.200(b) to include UF milk as a basic dairy ingredient.

Chobani made additional arguments with respect to safety, efficiency, and consistency with other foods standards, but did not request a hearing on them. Nevertheless, we address these arguments here. With respect to safety, Chobani asserted that approaches to using UF milk in the manufacture of yogurt ''result in no deleterious effects to safety'' (*Id.*).

We agree that UF milk is safe for use in the manufacture of yogurt and note that the final rule permits UF milk in the manufacture of yogurt as an optional dairy ingredient to increase the milk solids, not fat content (§ 131.200(a) and (c)). There is no genuine and substantial issue of fact with respect to the safety of UF milk in yogurt.

Chobani also asserted that using UF milk can result in greater production efficiency. While we recognize that operational efficiency is beneficial to a manufacturer, is not material to whether a food standard promotes honesty and fair dealing in the interest of consumers under section 401 of the FD&C Act and therefore does not present a genuine and substantial issue of fact.

Chobani also stated that permitting UF milk in yogurt would create consistency with U.S. and international standards for dairy foods. Regarding U.S. standards, Chobani stated that use of UF milk is already permitted in cheesemaking. Although we issued a proposed rule in 2005 to permit the use of UF milk in standardized cheeses and related cheese products (70 FR 60751), we have not finalized the rule. However, cheese and yogurt are different foods. Assuming that the use of UF milk as an ingredient in cheese or certain cheeses is consistent with the basic nature and essential characteristics of cheese or certain cheeses, it does not follow that the use of UF milk as a basic dairy ingredient in yogurt is consistent with the basic nature and essential characteristics of yogurt.

Finally, Chobani asserted that permitting the use of UF milk in the yogurt standard of identity would be consistent with international standards for yogurt. It is unclear to which international standards Chobani is referring. International standards do not reflect yogurt products sold in the United States or reflect American consumers' expectations about yogurt and therefore their existence is not a sufficient basis for amending our standards. Chobani has not provided evidence that harmonization with international standards promotes honesty and fair dealing in the interest of American consumers.

Since the filing of their objection on July 22, 2022, Chobani submitted an application for a Temporary Marketing Permit (TMP) in accordance with § 130.17 to market test lower fat yogurt deviating from the general definition and standard of identity (§ 130.10) and yogurt deviating from the yogurt standard of identity (§ 131.200) by using UF milk as a basic dairy ingredient under § 131.200(b). This will allow Chobani to gather appropriate supporting data to present to us in the future. As of November 2022, we are continuing to consider Chobani's TMP application.

IV. Summary and Conclusions

After evaluating the objections from IDFA, we are denying the requests for a hearing discussed in sections III.B–E. With respect to the request for a hearing on the provision in § 131.200(a) of the final rule requiring either a minimum titratable acidity or a maximum pH, we have issued a proposed order to IDFA under § 12.24(d) proposing to deny the request for a hearing under § 12.24(b)(1). We are denying the requests for a hearing with respect to vitamin D addition and the use of non-nutritive sweeteners because we agree with IDFA's proposed modifications and so there are no genuine and substantial issues of fact for resolution at a hearing (§ 12.24(b)(1)). We have modified § 131.200(d)(8) to permit vitamin D addition such that yogurt contains at least 10 percent DV per RACC of vitamin D, within limits of current good manufacturing practices. We have also modified § 131.200(d)(2) to permit both nutritive sweeteners and non-nutritive sweeteners, under the term ''sweeteners,'' as optional ingredients in yogurt.

We are denying IDFA's request for a hearing with respect to the addition of cream after culturing under § 12.24(b)(2), (3), and (4) due to insufficiency of the evidence submitted by IDFA. We also deny IDFA's requests for a hearing with respect to the 3.25 percent minimum milkfat requirement and the use of fat-containing flavoring ingredients to replace milkfat in yogurt and lower fat yogurt under § 12.24(b)(3) because the data and information submitted by IDFA are insufficient to justify that milkfat does not contribute to the basic nature and essential characteristics of yogurt and lower fat yogurt. However, we have modified the final rule to permit fat-containing flavoring ingredients in lower fat yogurt above the required minimum milkfat content and to permit the manufacture of yogurt with milkfat content less than 3.25 percent but at least 2.44 percent. These modifications are made to § 130.10(e) and § 131.200(g), respectively. Thus, insofar as IDFA's objection regarding the use of fat-containing flavoring ingredients pertains to increasing the fat content above the required minimum milkfat content of lower fat yogurt, we deny IDFA's objection under § 12.24(b)(1) as there is no genuine and substantial issue of fact for resolution at a hearing.

We are also denying Chobani's requests for a hearing with respect to the use of UF milk as a basic dairy ingredient in yogurt. The requests are denied under § 12.24(b)(2), (3), and (4) as explained above.

We have completed our evaluation of the objections in sections III.B–F and provided our bases under § 12.24(b) for denying the requests for a hearing stated therein. We conclude that this document constitutes final action on these objections under § 12.28(d). Therefore, notice is given that these objections and requests for a hearing do not form a basis for further stay of the effectiveness of the final rule announced in the **Federal Register** of March 23, 2022 (87 FR 16394). Accordingly, we are ending the stay of the final rule, except with respect to the provision of § 131.200(a) requiring a minimum titratable acidity or maximum pH, and amending certain portions of § 130.10 and § 131.200 as described. This final rule is effective as of [DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]. Objections to and requests for hearing on the amendments may be submitted under §§ 12.20 through 12.22 in accordance with § 12.26.

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public

display at *https://www.regulations.gov* because they have copyright restriction, or they are available as published articles and books. Please contact either person identified in the **FOR FURTHER INFORMATION CONTACT** section to schedule a date to inspect references without asterisks. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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List of Subjects

21 CFR Part 130

Food additives, Food grades and standards.

21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 130 and 131 are amended as follows:

PART 130—FOOD STANDARDS: GENERAL

■ 1. The authority citation for part 130 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 341, 343, 371.

■ 2. In § 130.10, redesignate paragraphs (e) and (f) as paragraphs (f) and (g) and add new paragraph (e) to read as follows:

§ 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

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(e) *Yogurt with modified milkfat and fat-containing flavoring ingredients.* Fat-containing flavoring ingredients may be added to yogurt for which the milkfat content has been modified in accordance with the expressed nutrient content claim regulations in § 101.62(b) of this chapter. The name of the food includes the term ''____ yogurt,'' the blank being filled in with the nutrient content claim in § 101.62(b)(1)(i), (b)(2)(i), or (b)(4)(i) of this chapter corresponding to the milkfat content, and a descriptor of the fat-containing flavoring ingredient(s).

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PART 131—MILK AND CREAM

■ 3. The authority citation for part 131 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

■ 4. In § 131.200:
■ a. Lift the stay for paragraphs (a), (b), (c), (d)(2), and (d)(8)(ii);
■ b. Revise paragraphs (d)(2) and (d)(8)(ii);
■ c. Redesignate paragraphs (g) and (h) as paragraphs (h) and (i);
■ d. Add new paragraph (g).
■ e. In newly redesignated paragraph (i) introductory text, remove ''in this paragraph (h)'' and add in its place ''in this paragraph (i)'' and

The revisions and addition read as follows:

§ 131.200 Yogurt.

* * * * *

(d) * * *

(2) Sweeteners.

* * * * *

(8) * * *

(ii) If added, vitamin D must be present in such quantity that the food contains not less than 10 percent Daily Value per Reference Amount Commonly Consumed (RACC) thereof, within limits of current good manufacturing practices.

* * * * *

(g) *Yogurt containing less than 3.25 percent milkfat.* (1) Yogurt may contain less than 3.25 percent milkfat and at least 2.44 percent milkfat. If the milkfat content is below 2.44 percent, the product is considered a modified food and is covered under § 130.10 of this chapter.

(2) Yogurt with milkfat content less than 3.25 percent and at least 2.44 percent milkfat, must be labeled with the following two phrases in the statement of identity, which must appear together:

(i) The word ''yogurt'' in type of the same size and style.

(ii) The statement ''____ percent milkfat,'' the blank being filled in with the nearest half percent to the actual milkfat content of the product. This statement of milkfat content must appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (g)(2)(i) of this section, but in no case less than one-eighth of an inch in height.

(3) Yogurt with milkfat less than 3.25 percent and at least 2.44 percent milkfat must comply with this standard, except that it may deviate as described in § 130.10 (b), (c), and (d) of this chapter.

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Dated: December 2, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–27040 Filed 12–14–22; 8:45 am]

BILLING CODE 4164–01–P