eye droppers, and ophthalmic dispensers are regulated as drugs when packaged with ophthalmic drugs is now obsolete, because these articles meet the ''device'' definition. Accordingly, an ophthalmic dispenser that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)) and that is packaged together with an ophthalmic drug is now regulated as a device constituent part (see § 3.2(e)), and, as such, is subject to the requirements in part 4. Because the drug constituent part provides the primary mode of action of these combination products, generally FDA's Center for Drug Evaluation and Research (CDER) will have primary jurisdiction over these products.

This change impacts products subject to pending applications,[2] approved products, and products marketed pursuant to section 505G of the FD&C Act (21 U.S.C. 355h) without an approved application under section 505 of the FD&C Act (21 U.S.C. 355) (commonly referred to as over-the-counter monograph drugs).

We recognize that some applicants and manufacturers may need to develop policies and procedures necessary to comply with the requirements in part 4. Therefore, we are issuing the guidance to communicate FDA's compliance policy with respect to these products. The guidance explains FDA's policy with respect to compliance with the requirements of part 4. Specifically, the guidance explains that FDA generally does not intend to take action with respect to noncompliance with part 820 (21 CFR part 820) as described in part 4, subpart A, with respect to ophthalmic products that were not previously regulated as combination products because of the now obsolete language in § 200.50(c) for a period of 12 months following the publication of the guidance. Further, the guidance explains that, with respect to ophthalmic products affected by the *Genus* decision that incorporate lower-risk device constituent parts, for example, eye dropper bottles/ampules that administer the drug directly to the eye, FDA does not intend to take action with respect to noncompliance with any applicable part 820 requirements for these products until FDA further considers the application of these requirements to these combination products. Additionally, the guidance describes FDA's policy with respect to pending applications and how FDA will determine when compliance with the requirements of part 4, subpart A, must be demonstrated (*i.e.,* during the review of the application or after approval). As part of this notice, FDA is soliciting feedback from stakeholders as to whether a 12-month period is sufficient for affected stakeholders to develop and implement the policies and procedures necessary to comply with the requirements of part 4, including whether different amounts of time should be considered with respect to compliance with subpart A and subpart B of part 4. Finally, in addition to the guidance for industry we are announcing today, FDA also encourages applicants and manufacturers to review other guidances for industry that apply to CDER-led drug-device combination products.

This guidance is being issued consistent with FDA's GGP regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR part 4.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

[2] For the purposes of this guidance, pending applications include applications on which FDA has taken an action that is not an approval action and that are not currently pending review before the Agency (*i.e.,* applications that have been tentatively approved or applications that have received a complete response letter) and applications currently pending review before the Agency (including supplements to approved applications).

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The collections of information in 21 CFR 600.80 and 600.81 are approved under OMB control number 0910–0308. The collections of information in 21 CFR 606.171 are approved under OMB control number 0910–0458. The collections of information in 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The collections of information in 21 CFR 806.10 and 802.20 are approved under OMB control number 0910–0359. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073. The collections of information in 21 CFR parts 606 and 640 are approved under OMB control number 0910–0116. The collections of information in 21 CFR part 610 are approved under OMB control numbers 0910–0116 and 0910–0338 (also for 21 CFR part 680 and Form FDA 356h). The collections of information in 21 CFR part 1271, subparts C and D, are approved under OMB control number 0910–0543. The collections of information in 21 CFR 4.102, 4.103, and 4.105 are approved under OMB control number 0910–0834.

## III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 11, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–05776 Filed 3–22–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 14

**[Docket No. FDA–2019–N–4203]**

## Advisory Committee; Bone, Reproductive and Urologic Drugs Advisory Committee; Change of Name and Function; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is amending the standing advisory committees' regulations to change the name and function of the Bone, Reproductive and Urologic Drugs Advisory Committee. This action is being taken to reflect changes made to the charter for this advisory committee.

**DATES:** This rule is effective March 23, 2022. The changes are applicable March 23, 2022.

**FOR FURTHER INFORMATION CONTACT:** Teresa Hays, Committee Management Officer, Food and Drug Administration,

10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8220.

**SUPPLEMENTARY INFORMATION:** FDA is announcing that the name of the Bone, Reproductive and Urologic Drugs Advisory Committee, which was established on March 23, 1978, has been changed. The Agency decided that the name ''Obstetrics, Reproductive and Urologic Drugs Advisory Committee'' more accurately describes the subject areas for which the committee is responsible. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs. The mandate of the committee no longer includes osteoporosis and metabolic bone disease. As osteoporosis and metabolic bone diseases are topics related to endocrinology and metabolic disease, these will be discussed by the Endocrinologic and Metabolic Drugs Advisory Committee.

The Obstetrics, Reproductive and Urologic Drugs Advisory Committee name was changed, and its functions changed in the charter renewal dated March 23, 2022. In this final rule, FDA is revising 21 CFR 14.100(c)(9) to reflect these changes.

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(B) and (d)(3) and 21 CFR 10.40(d) and (e)(1), the Agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest because the final rule is merely codifying the new name and the function of the advisory committee to reflect the current committee charter.

**List of Subjects in 21 CFR Part 14**

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

## PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

■ 2. Section 14.100 is amended by revising paragraph (c)(8) heading and paragraph (c)(8)(ii) to read as follows:

**§ 14.100 List of standing advisory committees.**

* * * * *

(c) * * *

(8) *Obstetrics, Reproductive and Urologic Drugs Advisory Committee.*

* * * * *

(ii) Function: The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

* * * * *

Dated: March 16, 2022.

**Andi Lipstein Fristedt,**

*Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.*

[FR Doc. 2022–05965 Filed 3–22–22; 8:45 am]

**BILLING CODE 4164–01–P**

## 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**

## Milk and Cream; Petition for an Administrative Stay of Action: Definitions and Standards of Identity for Yogurt, Lowfat Yogurt, and Nonfat Yogurt

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; notification of administrative stay.

**SUMMARY:** The Food and Drug Administration (FDA or we) is providing notice of a stay of the effectiveness of certain provisions of a final rule published in the **Federal Register** of June 11, 2021. The final rule amended the definition and standard of identity for yogurt and revoked the definitions and standards of identity for lowfat yogurt and nonfat yogurt. FDA is publishing this notification in response to objections timely filed in accordance with regulatory requirements.

**DATES:** FDA is administratively staying certain provisions in the final rule published on June 11, 2021 (86 FR 31117). FDA will publish a document in the **Federal Register** lifting the stay or taking further action as needed.

**ADDRESSES:** For access to the docket, 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, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:** Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of June 11, 2021 (86 FR 31117), FDA issued a final rule (the 2021 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). The 2021 final rule's effective date was July 12, 2021. Pursuant to section 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(e)), the 2021 final rule notified persons who would be adversely affected by the 2021 final rule that they could file objections, specifying with particularity the provisions of the 2021 final rule deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections.

The International Dairy Foods Association (IDFA) and Chobani timely filed objections and requests for a hearing with respect to several provisions in the 2021 final rule (see Objections and Request for Hearings submitted by Michael Dykes, DVM, 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) and Objection and Requests for Hearing submitted by Matthew Graziose, Ph.D., 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)). Section 701(e)(2) of the FD&C Act provides that, until final action is taken by the Secretary, the filing of objections