§ 157.208(d) and Table II of § 157.215(a), are hereby issued.

Effective Date

This final rule is effective March 23, 2022. The provisions of 5 U.S.C. 804 regarding Congressional review of Final Rules does not apply to the Final Rule because the rule concerns agency procedure and practice and will not substantially affect the rights or obligations of non-agency parties. The Final Rule merely updates amounts published in the Code of Federal Regulations to reflect the Department of Commerce's latest annual determination of the Gross Domestic Product (GDP) implicit price deflator, a mathematical updating required by the Commission's existing regulations.

List of Subjects in 18 CFR Part 157

Administrative practice and procedure, Natural gas, Reporting and recordkeeping requirements.

Issued: March 15, 2022.

Terry L. Turpin,

Director, Office of Energy Projects.

Accordingly, 18 CFR part 157 is amended as follows:

PART 157—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY AND FOR ORDERS PERMITTING AND APPROVING ABANDONMENT UNDER SECTION 7 OF THE NATURAL GAS ACT

■ 1. The authority citation for part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

■ 2. In § 157.208(d), revise Table I to read as follows:

§ 157.208 Construction, acquisition, operation, replacement, and miscellaneous rearrangement of facilities.

* * * * *

(d) * * *

TABLE I TO PART 157

Year	Limit	
	Auto. proj. cost limit (col. 1)	Prior notice proj. cost limit (col. 2)
1982	$4,200,000	$12,000,000
1983	4,500,000	12,800,000
1984	4,700,000	13,300,000
1985	4,900,000	13,800,000
1986	5,100,000	14,300,000
1987	5,200,000	14,700,000
1988	5,400,000	15,100,000
1989	5,600,000	15,600,000
1990	5,800,000	16,000,000
1991	6,000,000	16,700,000

TABLE I TO PART 157—Continued

Year	Limit	
	Auto. proj. cost limit (col. 1)	Prior notice proj. cost limit (col. 2)
1992	6,200,000	17,300,000
1993	6,400,000	17,700,000
1994	6,600,000	18,100,000
1995	6,700,000	18,400,000
1996	6,900,000	18,800,000
1997	7,000,000	19,200,000
1998	7,100,000	19,600,000
1999	7,200,000	19,800,000
2000	7,300,000	20,200,000
2001	7,400,000	20,600,000
2002	7,500,000	21,000,000
2003	7,600,000	21,200,000
2004	7,800,000	21,600,000
2005	8,000,000	22,000,000
2006	9,600,000	27,400,000
2007	9,900,000	28,200,000
2008	10,200,000	29,000,000
2009	10,400,000	29,600,000
2010	10,500,000	29,900,000
2011	10,600,000	30,200,000
2012	10,800,000	30,800,000
2013	11,000,000	31,400,000
2014	11,200,000	31,900,000
2015	11,400,000	32,400,000
2016	11,600,000	32,800,000
2017	11,800,000	33,200,000
2018	12,000,000	33,800,000
2019	12,300,000	34,600,000
2020	12,500,000	35,200,000
2021	12,600,000	35,600,000
2022	13,100,000	37,100,000

* * * * *

■ 3. In § 157.215(a)(5), revise Table II to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

(5) * * *

TABLE II TO PART 157

Year	Limit
1982	$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000
1996	4,300,000
1997	4,400,000
1998	4,500,000
1999	4,550,000
2000	4,650,000
2001	4,750,000
2002	4,850,000
2003	4,900,000

TABLE II TO PART 157—Continued

Year	Limit
2004	5,000,000
2005	5,100,000
2006	5,250,000
2007	5,400,000
2008	5,550,000
2009	5,600,000
2010	5,700,000
2011	5,750,000
2012	5,850,000
2013	6,000,000
2014	6,100,000
2015	6,200,000
2016	6,300,000
2017	6,400,000
2018	6,500,000
2019	6,600,000
2020	6,700,000
2021	6,800,000
2022	7,100,000

* * * * *

[FR Doc. 2022–06085 Filed 3–22–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA–2022–D–0192]

Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR Part 4; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR part 4.'' This guidance describes FDA's compliance policy with respect to the requirements of FDA regulations that are now applicable to ophthalmic drugs that are packaged with eye cups, eye droppers, and other dispensers intended for ophthalmic use.

DATES: The announcement of the guidance is published in the **Federal Register** on March 23, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 comments submitted to the Dockets Management Staff, FDA will post your comment, 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–2022–D–0192 for ''Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR part 4.'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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.'' The Agency will review this copy, including the claimed confidential information, in its 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.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930, *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR part 4.'' We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because FDA needs to communicate its compliance policy in a timely manner given the urgency of these issues following the decision from the U.S. Court of Appeals for the District of Columbia Circuit in *Genus Medical Technologies LLC* v. *U.S. Food and Drug Administration* (*Genus*), 994 F.3d 631 (D.C. Cir. 2021). Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices (GGP) regulation and FDA will consider all comments received and determine whether revisions to the guidance document are appropriate (§ 10.115(g)(3)).

In accordance with § 200.50(c) (21 CFR 200.50(c)), eye cups, eye droppers, and other dispensers intended for ophthalmic use (collectively referred to as ophthalmic dispensers) have been regulated as drugs when packaged together with the ophthalmic drug with which they were intended to be used. Therefore, products consisting of an ophthalmic drug packaged with an ophthalmic dispenser were not regulated as combination products as defined in § 3.2(e) (21 CFR 3.2(e)) and were not subject to the requirements of part 4 (21 CFR part 4). This practice is a departure from how FDA generally regulates other devices that are packaged with the drugs with which they are intended to be used. Specifically, when a device is packaged together with the drug with which it is intended to be used, FDA regulates that drug and the device together as a combination product (see § 3.2(e)).

On April 16, 2021, the U.S. Court of Appeals for the District of Columbia Circuit issued its decision in *Genus.* The *Genus* court stated ''[e]xcepting combination products, . . . devices must be regulated as devices and drugs—if they do not also satisfy the device definition—must be regulated as drugs.'' [1] In implementing this decision, FDA has determined that the language in § 200.50(c) indicating that eye cups,

[1] For more information on FDA's implementation of the *Genus* decision, please see Docket No. FDA–2021–N–0843, ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments,'' (86 FR 43553, August 9, 2021).

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,