TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [1]
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2).	0.1	1	0.1	200	20
Clinical images; facility [2]—900.4(c), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	1.44	4,154
Clinical images; AB [3]—900.4(c)	5	1	5	416	2,080
Phantom images; facility [2]—900.4(d), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	0.72 (43 minutes)	2,077
Phantom images; AB [3]—900.4(d)	5	1	5	208	1,040
Annual equipment evaluation and survey; facility [2]—900.4(e), 900.11(b)(1), and 900.11(b)(2).	8,718	1	8,718	1	8,718
Annual equipment evaluation and survey; AB [3]—900.4(e).	5	1	5	1,730	8,650
Provisional mammography facility certificate extension application—900.11(b)(3).	0	1	0	0.5 (30 minutes)	1
Mammography facility certificate reinstatement application—900.11(c).	281	1	281	5	1,405
Lay summary of examination—900.12(c)(2)	8,718	5,085	44,331,030	0.083 (5 minutes)	3,679,475
Lay summary of examination; patient refusal [4]—900.12(c)(2).	87	1	87	0.5 (30 minutes)	44
Report of unresolved serious complaints—900.12(h)(4).	20	1	20	1	20
Information regarding compromised quality; facility [2]—900.12(j)(1).	20	1	20	200	4,000
Information regarding compromised quality; AB [3]—900.12(j)(1).	20	1	20	320	6,400
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500
Reconsideration of accreditation—900.15(c)	5	1	5	2	10
Notification of requirement to correct major deficiencies—900.24(a).	0.4	1	0.4	200	80
Notification of loss of approval; major deficiencies—900.24(a)(2).	0.15	1	0.15	100	15
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60
Notification of loss of approval; minor deficiencies—900.24(b)(3).	0.15	1	0.15	100	15
Total					3,718,764

[1] Total hours have been rounded.
[2] Refers to the facility component of the burden for this requirement.
[3] Refers to the AB component of the burden for this requirement.
[4] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Respondents use the Mammography Program Reporting and Information System to submit information. Our estimated burden for the information collection reflects an overall increase of 28,664 hours and a corresponding increase of 9,137,449 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years. We do not include burden for §§ 900.12(c)(1) and (3), 900.3(f)(1), and 900.24(c) because if a certifying State had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying State's electronic records, we assume no additional reporting burden.

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23028 Filed 10–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2101]

Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry.'' Neurodegenerative diseases are a heterogeneous group of disorders characterized by progressive degeneration of the structure and function of the central nervous system or peripheral nervous system. The guidance document provides recommendations to sponsors developing human gene therapy (GT) products for neurodegenerative diseases affecting adult and pediatric patients. The guidance focuses on considerations for product development, preclinical testing, and clinical trial design. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on October 24, 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–2020–D–2101 for ''Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry.'' 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry.'' Neurodegenerative diseases are a heterogeneous group of disorders characterized by progressive degeneration of the structure and function of the central nervous system or peripheral nervous system. These diseases vary in etiology, prevalence, diagnosis, and management, and include genetic as well as age-related diseases. The guidance document provides recommendations to sponsors developing a GT product for neurodegenerative diseases affecting adult and pediatric patients. The guidance focuses on considerations for product development, preclinical testing, and clinical trial design.

In the **Federal Register** of January 6, 2021 (86 FR 549), FDA announced the availability of the draft guidance of the same title dated January 2021. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifications to the recommendations regarding use of tumorigenic cell lines, comparability studies, and crossover designs for clinical trials. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated January 2021.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Human Gene Therapy for Neurodegenerative Diseases.'' 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.

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 50 have been

approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in the guidance entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765.

III. Electronic Access

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

Dated: October 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23057 Filed 10–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances for developing topical products applied to the skin, as well as integumentary and mucosal (*e.g.,* vaginal) membranes. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidances by December 23, 2022 to ensure that the Agency considers your comment on these draft guidances before it begins work on the final versions of the guidances.

ADDRESSES: You may submit comments on any guidance 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research (HFD–880), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–