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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product BRINEURA (cerliponase alfa). BRINEURA is indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2, also known as tripeptidyl peptidase 1 deficiency. Subsequent to this approval, the USPTO received a patent term restoration application for BRINEURA (U.S. Patent No. 8,029,781) from Rutgers, the State University of New Jersey, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 2, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of BRINEURA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BRINEURA is 995 days. Of this time, 659 days occurred during the testing phase of the regulatory review period, while 336 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* August 8, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 8, 2014.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 27, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for BRINEURA (BLA 761052) was initially submitted on May 27, 2016.

3. *The date the application was approved:* April 27, 2017. FDA has verified the applicant's claim that BLA 761052 was approved on April 27, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 666 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22559 Filed 10–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2613]

Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements; Draft 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 draft guidance for industry entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements.'' This draft guidance provides recommendations for presenting quantitative efficacy and risk information in direct-to-consumer (DTC) promotional labeling and advertisements for prescription human drugs and biological products and prescription animal drugs and in DTC promotional labeling for over-the-counter (OTC) animal drugs (collectively *promotional materials*). FDA is issuing this draft guidance to describe the Agency's recommendations for how manufacturers, distributers, and packers (collectively *firms*) that include quantitative efficacy or risk information about their drugs in DTC promotional materials can make the language and presentation more consumer-friendly.

DATES: Submit either electronic or written comments on the draft guidance by December 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–2018–D–2613 for ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements; Draft Guidance for Industry; Availability.'' 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.

- 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.gpo.gov/fdsys/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.

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 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; or the 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 the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pepinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3248, Silver Spring, MD 20993–0002, 301–796–1200; or Stephen Ripley, 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; or Tom Moskal, Center for Veterinary Medicine (HFV–216), 7519 Standish Pl., Rockville, MD 20855, 240–402–6251.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements.'' This draft guidance describes recommendations for how firms that include quantitative efficacy or risk information about their drugs [1] in DTC promotional materials can make the language and presentation more consumer-friendly. These recommendations apply to DTC promotional materials covered by this draft guidance regardless of the medium in which they are presented (*e.g.,* print, electronic, audiovisual, broadcast).

When describing efficacy and risk information about a drug in promotional materials, firms generally have flexibility with how they present this information so long as the presentation is balanced, truthful, and non-misleading, and complies with other applicable statutory and regulatory requirements. One consideration for firms as they develop DTC promotional materials for their drugs is how to best convey efficacy and risk information in a manner that consumers can easily understand, including whether to use words, numbers, visual graphics, or a combination of these elements. FDA understands that firms may experience challenges in determining how to best present quantitative efficacy or risk information in their DTC promotional materials so that consumers can easily comprehend it and use it to form accurate perceptions about their drugs. For these reasons, FDA is issuing this

[1] The term *drugs* in this guidance refers to prescription human drugs, including prescription biological products, and prescription and OTC animal drugs.

draft guidance to provide recommendations for presenting quantitative efficacy and risk information in DTC promotional materials and to encourage firms to follow these recommendations when including such information in their DTC promotional materials.

The draft guidance covers the following topics for presenting quantitative efficacy and risk information in DTC promotional materials, based on current research findings related to communicating health information:

- Presenting probability information in terms of absolute frequencies, percentages, and relative frequencies
- Formatting quantitative efficacy or risk information
- Using visual aids to illustrate quantitative efficacy or risk information
- Providing quantitative efficacy or risk information for the treatment group and the control group

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's recommendations for ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors and their representatives (firms) of human prescription drugs, including prescription biological products, and animal prescription and OTC drugs.

Burden Estimate: The draft guidance provides recommendations on how firms should present quantitative efficacy and risk information in their DTC promotional materials. Accordingly, the draft guidance recommends a ''third-party disclosure'' that constitutes a ''collection of information'' under the PRA.

Specifically, the draft guidance recommends that firms display quantitative efficacy or risk information in specific numeric formats (*e.g.,* absolute frequencies or percentages; whole numbers; denominators with a base of 10) and with appropriate context (*e.g.,* adding absolute frequency presentations to relative frequency presentations); provides formatting considerations for illustrating quantitative efficacy or risk information in a visual aid; and recommends that firms include quantitative efficacy or risk information about the control group when it is provided for the treatment group in DTC promotional materials.

According to FDA data, approximately 40,000 FDA-regulated DTC promotional materials are prepared by approximately 404 firms annually, and of these materials, the Agency estimates that approximately 40 percent contain presentations of quantitative efficacy or risk information. Based on this information, FDA estimates that approximately 40 percent (160) firms will disseminate 16,000 DTC promotional materials that contain quantitative efficacy or risk information annually, and therefore may be subject to the third-party disclosures. Based on its experience reviewing FDA-regulated promotional materials for drugs, FDA estimates that it will take firms approximately 2 hours to make the disclosures recommended in the draft guidance if they choose to include quantitative efficacy or risk information in their DTC promotional materials and follow the recommendations of this guidance.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of information	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recommended information to be included when firms disseminate promotional materials that contain quantitative efficacy or risk information	160	100	16,000	2	32,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm*, or *https://www.regulations.gov.*

Dated: October 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22568 Filed 10–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1018]

Isachi Gil; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Isachi Gil's (Gil's) request for a hearing and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Gil for 6 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Gil was convicted of 12 felonies under Federal Law involving fraud or falsification and that Gil has demonstrated a pattern of conduct sufficient to find that there is reason to believe she may violate requirements under the FD&C Act relating to drug products. In determining the appropriateness and period of Gil's debarment, FDA considered the relevant factors listed in the FD&C Act. Gil failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable October 17, 2018.

ADDRESSES: Any application for termination of debarment by Gil under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: Your application must include the Docket No. FDA–2013–N–1018. An application will be placed in the docket and, unless 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.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: 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: Rachael V. Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits FDA to debar an individual if it finds that the individual: (1) Has been convicted of a felony that involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense and (2) based on the conviction and other information, has demonstrated a pattern of conduct sufficient to find that there is reason to believe that the person may violate requirements under the FD&C Act relating to drug products.

On May 24, 2011, a jury found Gil guilty of 12 felonies. On September 28, 2011, the U.S. District Court for the Southern District of Florida entered judgment against her for five counts of felony healthcare fraud, in violation of 18 U.S.C. 1347, and seven counts of felony false statements related to healthcare matters, in violation of 18 U.S.C. 1035(a)(2). The court sentenced Gil to 43 months in prison, with 3 years of supervised release.

Gil's convictions stemmed from her work as a registered nurse in the home health field. From around March 14, 2007, through about July 15, 2009, Gil worked as a registered nurse, employed by a nursing staffing company and local home health agencies. During this time, Gil knowingly and willfully submitted and caused the submission of false and fraudulent claims to Medicare, seeking reimbursement for various home health services she had not provided. Specifically, Gil falsified and caused