must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (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.

**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 REBINYN (Coagulation Factor IX (Recombinant) GlycoPEGylated). REBINYN is indicated for use in adults and children with hemophilia B for: (1) On-demand treatment and control of bleeding episodes, and (2) Perioperative management of bleeding. Subsequent to this approval, the USPTO received a patent term restoration application for REBINYN (U.S. Patent Nos. 7,138,371 and 7,179,617) from Novo Nordisk A/S, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 6, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of REBINYN 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 REBINYN is 2,793 days. Of this time, 2,412 days occurred during the testing phase of the regulatory review period, while 381 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:* October 9, 2009. The applicant claims May 16, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 9, 2009, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

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 16, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for REBINYN (BLA 125611/0) was initially submitted on May 16, 2016.

3. *The date the application was approved:* May 31, 2017. FDA has verified the applicant's claim that BLA 125611/0 was approved on May 31, 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 applications for patent extension, this applicant seeks 1,660 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 22, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23437 Filed 10–25–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2007–D–0369]**

### Product-Specific Guidance; Revised Draft Guidance for Industry on Sucralfate; Reopening of Comment Period

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

**ACTION:** Notice of availability; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is reopening the comment period for a

revised draft product-specific guidance on Sucralfate that appeared in a notice of availability, published in the **Federal Register** of October 20, 2017. In that notice, FDA requested comments on the revised draft guidance for industry on Sucralfate, as well as comments on other product-specific guidances. FDA is reopening the comment period for the Draft Guidance on Sucralfate (revised October 2017) to facilitate submission of comments pertaining to this draft guidance following an FDA response to two citizen petitions. The petition response suggests that the petitioners submit to the docket comments relating to the guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by December 26, 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–2007–D–0369 for ''Product-Specific Guidance; Revised Draft Guidance for Industry on Sucralfate; Reopening of Comment Period.'' 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. 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 document.

**FOR FURTHER INFORMATION CONTACT:** Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of October 20, 2017 (82 FR 48826), FDA published a notice of availability with a 60-day comment period to request comments on the revised draft guidance for industry on Sucralfate, as well as comments on other product-specific guidances. This draft guidance includes recommendations pertaining to abbreviated new drug applications seeking approval of sucralfate oral suspension products, 1 gram/10 milliliters.

The comment period for all draft guidances identified in that notice ended on December 19, 2017.

On December 18, 2017, FDA received a citizen petition from Haynes and Boone, LLP (Docket No. FDA–2017–P–6922), requesting that FDA deny approval to any abbreviated new drug application for a sucralfate oral suspension drug product that relies on patient-based clinical endpoint studies to establish bioequivalence with the reference listed drug. On March 28, 2018, FDA received a citizen petition from Vertice Pharma (Docket No. FDA–2018–P–1310) requesting specific changes to the recommendations made in the ''Draft Guidance on Sucralfate'' (revised October 2017), available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573202.pdf.*

FDA denied both petitions in a joint response dated May 17, 2018. However, given the interest in this guidance, FDA is reopening the comment period until December 26, 2018. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

**II. Electronic Access**

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

Dated: October 22, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23386 Filed 10–25–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0430, 0431, 0432, 0433, 0434]**

## Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before November 26, 2018.

**ADDRESSES:** Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Crime Control Act—Requirement for Background Checks.

*Type of Collection:* Extension.

*OMB No.:* 0990–0430—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

*Abstract:* Crime Control Act—Requirement for Background Checks: Performance of HHS mission requires the support of contractors. In some circumstances, depending on the requirements of the specific contract, the contractor is tasked to provide personnel who will be working with children under the age of 18. After contract award, contractor personnel must undergo a criminal background check as required by HHS Acquisition Regulation (HHSAR) 337.103(d)(3) and the clause at HHSAR 352.237–72 Crime Control Act—Requirement for Background Checks before working on the contract as required by federal law (Crime Control Act of 1990). The contractor is therefore required to provide a list of the names of its relevant personnel for purposes of enabling HHS to conduct a criminal background check.

The Agency is requesting a 3 year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

| Type of respondent | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| Business (contractor) | 160 | 1 | 1 | 160 |
| Total | 160 | 1 | 1 | 160 |

*Title of the Collection:* Acquisitions Involving Human Subjects.

*Type of Collection:* Extension.

*OMB No.:* 0990–0431—Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy, and Accountability, Division of Acquisition.

*Abstract:* Acquisitions Involving Human Subjects: Performance of HHS mission requires the support of contractors involving human subjects. Before awarding a contract to any contractor that will need to use human subjects, the Contracting Officer is required to verify that, the contractor holds a valid Federal Wide Assurance (FWA) approved by the Office for Human Research Protections (OHRP), as described in HHSAR Subpart 370.3—Acquisitions Involving Human Subjects. The provisions are implemented via contract clauses found at HHSAR 352.270–4a (Protection of Human Subjects), the clause at HHSAR 352.270–4b (Protection of Human Subjects), the provision at HHSAR 352.270–10 (Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required), and the clause at HHSAR 352.270–11 (Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required).

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

ESTIMATED ANNUALIZED BURDEN TABLE

| Type of respondent | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| Business (contractor) | 90 | 4 | 5 | 1,800 |