''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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product EUCRISA (crisaborole). EUCRISA indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. Subsequent to this approval, the USPTO received patent term restoration applications for EUCRISA (U.S. Patent Nos. 8,039,451 and 8,168,614) from Anacor Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 6, 2017, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of EUCRISA 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 EUCRISA is 3,121 days. Of this time, 2,778 days occurred during the testing phase of the regulatory review period, while 343 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* May 31, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was May 31, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* January 7, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for EUCRISA (NDA 207695) was initially submitted on January 7, 2016.

3. *The date the application was approved:* December 14, 2016. FDA has verified the applicant's claim that NDA 207695 was approved on December 14, 2016.

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 328 days or 1,114 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: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01956 Filed 2–11–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2969]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Assessment of Combination Product Review Practices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 14, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Assessment of Combination Product Review Practices.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD

20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Assessment of Combination Product Review Practices

OMB Control Number 0910–NEW

In 1991, FDA's Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health entered into ''Intercenter Agreements'' to provide guidance on the classification and assignment of medical products and to clarify jurisdiction over combination product reviews. With the enactment of the Medical Device User Fee and Modernization Act of 2002, FDA aimed to achieve prompt assignment of combination products, timely and effective premarket reviews, and consistent and appropriate postmarket regulation through the establishment of the Office of Combination Products (OCP). Since then, OCP has operated to further standardize combination product guidance to FDA and industry and facilitate coordination between FDA's medical product review Centers. As part of the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA committed to advance the development of drug-device and biologic-device combination products regulated by CDER and CBER through modernization of the combination product review program. To that end, FDA committed to contracting with an independent third party to assess current practices for combination drug product review, to include interviews with combination product sponsors and applicants. The contractor for the assessment of combination drug product review practices is Eastern Research Group, Inc. (ERG).

Therefore, in accordance with the PDUFA VI Commitment Letter, FDA proposes to have ERG conduct independent interviews of combination product sponsors and applicants during the data collection period as follows:

- Sponsors with a Request For Designation (RFD) or pre-RFD submitted during the data collection period.
- Sponsors with a combination product Investigational New Drug (IND) or pre-IND submitted during the data collection period.
- Applicants with a combination product New Drug Application (NDA) or Biologics License Application (BLA) that receives a first-cycle action from FDA during the data collection period.

The purpose of these interviews is to collect voluntary feedback from combination product sponsors and applicants on their experience with FDA during the development and review of their products, including any challenges or best practices. ERG will anonymize and aggregate sponsor/applicant responses prior to inclusion in the assessment. ERG will use interview responses to complement and supplement data on combination product review parameters obtained through other means, such as extraction of data from FDA corporate databases and interviews with FDA review staff. FDA will publish ERG's assessment (with interview results and findings) on the Agency's public website and a link to the assessment in the **Federal Register** for public comment.

In the **Federal Register** of September 27, 2018 (83 FR 48822), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Sponsors submit approximately 150 to 180 RFDs/pre-RFDs and 200 to 240 combination product original INDs/pre-INDs per year. ERG will interview 1 to 3 sponsor representatives at a time for up to 35 RFDs/pre-RFDs and 48 INDs received by FDA—up to 105 RFD/pre-RFD and 144 IND/pre-IND sponsor representatives per year. FDA typically reviews approximately 25 to 30 combination product original NDAs and original BLAs per year. ERG will interview 1 to 3 applicant representatives at a time for each application that receives a first-cycle action from FDA—up to 90 representatives per year. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Pretest	5	1	5	1.5	7.5
Interviews	339	1	339	1.5	508.5
Total					516

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

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. FDA estimates that up to 339 respondents will take part in the interviews each year, with each interview lasting 1 to 1.5 hours, for a total of a maximum of 508.5 hours. Thus, the total estimated annual burden is 516 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01979 Filed 2–11–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4735]

Agency Information Collection Activities; Proposed Collection; Comment Request; Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.