2006, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 17, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for ENTRESTO (NDA 207620) was initially submitted on December 17, 2014.

3. *The date the application was approved:* July 7, 2015. FDA has verified the applicant's claim that NDA 207620 was approved on July 7, 2015.

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 1,296 days, 732 days, 519 days, 270 days or 225 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 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02592 Filed 2–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine

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 12, 2018.

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 0910–0566. 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.

Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine—21 CFR 10.75

OMB Control Number 0910–0566—Extension

The Center for Veterinary Medicine's (CVM's) Guidance for Industry (GIF) #79, ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine'' (*https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052393.pdf*), describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. The guidance details information on how CVM intends to apply provisions of existing regulations regarding internal review of Agency decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers of animal drugs or other products regulated by CVM that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established procedures discussed in the guidance.

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method then CVM recommends that the applicant follow the procedures in GFI #79.

In the **Federal Register** of October 27, 2017 (82 FR 49836), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75, Request for review of a scientific dispute	1	4	4	10	40

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

In the next 3 years, CVM anticipates receiving one or fewer requests for review of a scientific dispute per year, on average. We base our estimate on CVM's experience over the past 6 years in handling formal appeals for scientific disputes. The burden of this collection has changed. The number of respondents decreased from two to one annually, the number of responses per respondent remained at four annually, the hours per response remained at 10 annually, and the total number of hours decreased from 80 to 40. This decrease in the total hours is the result of a natural fluctuation in the number of respondents taking advantage of this dispute resolution process.

Dated: February 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02593 Filed 2–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0334]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

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 12, 2018.

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 0910–0770. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Postmarketing Safety Reports for Human Drug and Biological Products: Waivers From Electronic Submission Requirements

OMB Control Number 0910–0770—Extension

This information collection supports information collection found in FDA regulations. In the **Federal Register** of June 10, 2014 (79 FR 33072), FDA published a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements.'' The final rule amended FDA's postmarketing safety reporting regulations for human drug and biological products under 21 CFR parts 310, 314, and 600 and added part 329 to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. Specifically, this includes:

- Manufacturers; packers; distributors; applicants with approved new drug applications, abbreviated new drug applications, and biologics licensing applications (BLAs); and those that market prescription drugs for human use without an approved application must submit postmarketing safety reports to the Agency (§§ 310.305, 314.80, 314.98, and 600.80);
- manufacturers, packers, or distributors whose name appears on the label of nonprescription human drug products marketed without an approved application must report serious adverse events associated with their products (section 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379aa)); and
- applicants with approved BLAs must submit biological lot distribution reports to the Agency (§ 600.81).

Under §§ 310.305(e)(2), 314.80(g)(2), 329.100(c)(2), 600.80(h)(2), and 600.81(b)(2), of the regulations, those who are subject to these postmarketing safety reporting requirements may request a waiver from the electronic format requirement. While FDA currently has OMB approval for the collection of postmarketing safety reports,[1] this information collection supports respondents seeking waivers from submitting those reports in electronic format as required by the regulations.

In the **Federal Register** of October 30, 2017 (82 FR 50141), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

We therefore estimate the burden of this collection of information as follows:

[1] FDA currently has OMB approval for submission of postmarketing safety reports under parts 310, 314, and 600. The information collection for parts 310 and 314 is approved under OMB Control Numbers 0910–0291 and 0910–0230. The information collection for part 600 is approved under OMB Control Numbers 0910–0291 and 0910–0308. Submissions required by section 760 of the FD&C Act have been approved under OMB Control Number 0910–0636.