sent to the appropriate address listed in the guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier one DR or a request for tier two DR;
- Name and address of manufacturer inspected (as listed on FDA Form 483);
- Date of inspection (as listed on FDA Form 483);
- Date the FDA Form 483 was issued (from FDA Form 483);
- Facility Establishment Identifier (FEI) Number, if available (from FDA Form 483);
- FDA employee names and titles that conducted inspection (from FDA Form 483);
- Office responsible for the inspection (*e.g.,* district office, as listed on the FDA Form 483);
- Application number, if the inspection was a preapproval inspection;
- Comprehensive statement of each issue to be resolved;
- Identify the observation in dispute:
  - Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data.
  - State the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of the FDA Form 483.
  - Identify possible solutions.
  - State expected outcome.
- Name, title, telephone and FAX number, and e-mail address (as available) of manufacturer contact.

The guidance was part of the FDA initiative ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products. The Agency formed the Dispute Resolution Working Group comprising representatives from ORA, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine. The working group met weekly on issues related to the DR process and met with stakeholders in December 2002 to seek their input.

The guidance was initiated in response to industry's request for a formal DR process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained earlier in this document. The guidance also covers the following topics:

- The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.
- Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.
- Public availability of decisions reached during the DR process to promote consistent application and interpretation of drug quality-related regulations.

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: Based on the number of requests for tier one and tier two DRs received by FDA since the guidance published in January 2006, FDA estimates that approximately two manufacturers will submit approximately two requests annually for a tier one DR and that there will be one appeal of these requests to the DR panel (request for tier two DR). FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier one DR and approximately 8 hours to prepare and submit each request for a tier two DR. Table 1 of this document provides an estimate of the annual reporting burden for requests for tier one and tier two DRs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Requests for Tier One DR	2	1	2	30	60
Requests for Tier Two DR	1	1	1	8	8
Total					68

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

Dated: June 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15141 Filed 6–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0264]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

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 July 20, 2011.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0623. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle—(OMB Control Number 0910–0623)—Extension

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(a)) provides requirements with regard to imported food and cosmetics and provides for refusal of admission into the United States of human food and cosmetics that appear to be adulterated. Section 701(b) of the FD&C Act (21 U.S.C. 371(b)) authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act. To address the potential risk of bovine spongiform encephalopathy (BSE) in human food and cosmetics, FDA regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) designate certain materials from cattle as ''prohibited cattle materials,'' including specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS)(Beef). Under the regulations, no human food or cosmetic may be manufactured from, processed with, or otherwise contain prohibited cattle materials. However, the Agency may designate a country from which cattle materials inspected and passed for human consumption are not considered prohibited cattle materials and their use does not render a human food or cosmetic adulterated.

Sections 189.5(e) and 700.27(e) provide that a country seeking to be so designated must send a written request to the Director, Center for Food Safety and Applied Nutrition (CFSAN). The information the country is required to submit includes information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other information relevant to determining whether specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, or MS(Beef) from the country seeking designation should be considered prohibited cattle materials. FDA uses the information to determine whether to grant a request for designation, and whether to impose conditions if a request is granted.

Sections 189.5 and 700.27 further state that countries that have been designated under 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate. Therefore, designated countries may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. FDA uses the information to ensure that their designation remains appropriate.

This estimate is based on FDA's experience and the average number of requests for designation under 189.5 and 700.27 received in the past 3 years. FDA received 1 request for designation in 2009 and 1 in 2010. Based on this experience, FDA estimates the annual number of new requests for designation will be one. FDA estimates that preparing the information required by 189.5 and 700.27 and submitting it to the Agency in the form of a written request to the Director, CFSAN will require a burden of approximately 80 hours per request. Thus, the annual burden for new requests for designation is estimated to be 80 hours, as shown in table 1, row 1 of this document. Under 189.5(e) and 700.27(e), designated countries are subject to future review by FDA and may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. In the last 3 years, FDA has not requested any reviews. Thus, the Agency estimates that one or fewer will occur annually in the future. We estimate that the designated country undergoing a review in the future will need one third the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours (80 hours × 0.33 = 26.4 hours, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 2 of this document. The total annual burden for this information collection is estimated to be 106 hours.

In the **Federal Register** of April 15, 2011 (76 FR 21378), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
189.5 and 700.27—request for designation	1	1	1	80	80
189.5(e) and 700.27(e)—response to request for review by FDA	1	1	1	26	26
Total					106

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

Dated: June 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15142 Filed 6–17–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–E–0267 (formerly) 2004E–0325]

Determination of Regulatory Review Period for Purposes of Patent Extension; MYFORTIC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYFORTIC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 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. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: 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 Patents and Trademarks 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 approved for marketing the human drug product MYFORTIC (mycophenolate sodium). MYFORTIC is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MYFORTIC (U.S. Patent No. 6,306,900) from Novartis AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration and that FDA determine the product's regulatory review period. In a letter dated May 25, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MYFORTIC represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for MYFORTIC is 1,947 days. Of this time, 1,643 days occurred during the testing phase of the regulatory review period, while 304 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* October 31, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 31, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 30, 2003. FDA has verified the applicant's claim that the new drug application (NDA) for Myfortic (NDA 50–791) was submitted on April 30, 2003.

3. *The date the application was approved:* February 27, 2004. FDA has verified the applicant's claim that NDA 50–791 was approved on February 27, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 323 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 19, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 19, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (*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.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–15197 Filed 6–17–11; 8:45 am]

BILLING CODE 4160–01–P