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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0091]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions in the guidance document entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition."

**DATES:** Submit written or electronic comments on the collection of information by May 29, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** Under the 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, including each proposed extension of an existing 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.

#### Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (OMB Control Number 0910-0541)—Extension

As an integral part of its decisionmaking process, FDA is obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or

cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles. FDA also has eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, FDA has provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to CFSAN. The guidance document entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations.

FDA is requesting the extension of OMB approval for the information collection provisions in the guidance.

*Description of Respondents:* The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.32(i)	52	3	156	1	156
25.32(o)	1	1	1	1	1
25.32(q)	7	2	14	1	14
Total			171		171

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: March 22, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 2003E-0243 and 2003E-0244]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of two applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that medical device.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE. INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE (U.S. Patent Nos. 5,782,919 and 5,984,967) from SDGI Holdings, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE represented the first permitted