[FR Doc. E7–808 Filed 1–22–07; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0279]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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 February 22, 2007.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Bar Code Label Requirement for Human Drug and Biological Products—(OMB Control Number 0910–0537)—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA issued a new rule that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Center for Biologics Evaluation and Research Director as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR 9120 at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated in the final rule is now covered in other OMB-approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests submitted during 2004 and 2005, we estimate that approximately 2 waiver requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

In the **Federal Register** of July 24, 2006 (71 FR 41817), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.25(d)	2	1	2	24	48
Total					48

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

Dated: January 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–916 Filed 1–22–07; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 22, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Ronald P. Jean, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3676, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 22, 2007, the committee will discuss, make recommendations and vote on a

premarket approval application for the Cormet 2000 Hip Resurfacing System, sponsored by Corin U.S.A. This system is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative arthritis or inflammatory arthritis.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at*http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 8, 2007. Oral presentations from the public will be scheduled for 30 minutes at the beginning of the committee deliberations and for 30 minutes near the end of the deliberations on February 22, 2007. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 31, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 1, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at 301–827–7292 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 17, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–946 Filed 1–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Hydrogen Peroxide Solution for Control of Various Fungal and Bacterial Diseases in Fish; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, and environmental data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of a 35 percent solution of hydrogen peroxide by immersion for control of mortality in several life stages of certain freshwater-reared finfish species due to various fungal and bacterial diseases. The data, contained in Public Master File (PMF) 5639, were compiled by the United States Geological Survey, Biological Resources Section, Upper Midwest Environmental Sciences Center.

ADDRESSES: Submit NADAs or supplemental NADAs to the Document Control Unit (HFV–199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Joan Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Hydrogen peroxide solution used by immersion for control of mortality in several life stages of certain freshwater-reared finfish species due to various fungal and bacterial diseases is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, hydrogen peroxide is subject to section 512 of the act (21 U.S.C. 360b) which requires that its uses be the subject of an approved NADA or supplemental NADA. Fish are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The United States Geological Survey, Biological Resources Section, Upper Midwest Environmental Sciences Center, 2630 Fanta Reed Rd., La Crosse, WI 54603, has provided effectiveness and target animal safety data; and an environmental assessment (EA) for use of a 35 percent solution of hydrogen peroxide by immersion for control of mortality in certain freshwater-reared finfish species in several life stages due to various fungal and bacterial diseases. These data and the EA are contained in PMF 5639.

FDA has reviewed the EA, carefully considered the environmental impacts of the use of a 35 percent solution of hydrogen peroxide on freshwater finfish, and has concluded that the use will not have a significant impact on the human environment. A finding of no significant impact (FONSI) has been prepared and is also contained in PMF 5639.

Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5639 to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: data concerning human food safety; and manufacturing methods, facilities, and controls. Persons desiring more information concerning PMF 5639 or requirements for approval of an NADA or supplemental NADA may contact Joan C. Gotthardt (see **FOR FURTHER INFORMATION CONTACT**).

In accordance with the freedom of information provisions of 21 CFR part 20, a summary of safety and effectiveness data provided in PMF 5639 to support approval of an application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, from 9 a.m. to 4 p.m., Monday through Friday. The EA and FONSI contained in PMF 5639 have also been placed in the docket.

Dated: January 11, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7–947 Filed 1–22–07; 8:45 am]

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