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]

**BILLING CODE 4160–01–S**