II. Agenda

On Friday, October 25, 1996, the meeting will begin at 9:00 a.m. with the call to order by the Council Chairman. The Administrator, AHCPR, will update the status of current Agency issues and program initiatives. Council discussion will follow.

The meeting will adjourn at 4:00 p.m. Agenda items are subject to change as priorities dictate.

Dated: October 15, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–26923 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–90–M

Agency for Toxic Substances and Disease Registry

Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following committee meeting.

Name: Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry (BSC, ATSDR).

Times and Dates: 8:30 a.m.–5:30 p.m., November 14, 1996. 8:30 a.m.–2:15 p.m., November 15, 1996.

Place: The ATSDR Training Room, Building 35, 35 Executive Park Drive, NE, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 60 people.

Purpose: The Board of Scientific Counselors, ATSDR, advises the Administrator, ATSDR, on ATSDR programs to ensure scientific quality, timeliness, utility, and dissemination of results. Specifically, the Board advises on the adequacy of the science in ATSDR-supported research, emerging problems that require scientific investigation, accuracy and currency of the science in ATSDR reports, and program areas to emphasize and/or to de-emphasize.

Matters to be Discussed: Agenda items will include an update on the ATSDR Community/Tribal Forum and will also focus on other issues of concern to ATSDR including: 1) the ATSDR Peer Review Policy and Procedures; 2) external perspectives from chemical manufacturers, grantees, universities, states, and communities; 3) the ATSDR Site-Specific Evaluation Initiative; and 4) the ATSDR Child Health Initiative.

Written comments are welcome and should be received by the contact person listed below prior to the meeting.

Contact Person for More Information: Charles Xintaras, Sc.D., Executive Secretary, BSC, ATSDR, M/S E–28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0708.

Dated: October 11, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–26749 Filed 10–17–96; 8:45 am]

BILLING CODE 4163–70–M

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health; Notice of Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Laboratory Evaluation of Back Support Belts.

Time and Date: 1 p.m.–4 p.m., November 4, 1996.

Place: Suncrest Facility, Large Conference Room, NIOSH, CDC, 3040 University Avenue, Morgantown, West Virginia 26505.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: Participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the study protocol ''Laboratory Evaluation of Back Support Belts,'' being conducted at NIOSH. Peer review panelists will review the study protocol and provide individual advice on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other governmental agencies, and the public are invited.

Contact Person for Additional Information: Hongwei Hsiao, Ph.D., NIOSH, CDC, M/S P119, 3040 University Avenue, West Virginia 26505, telephone 304/285–5981.

Dated: October 11, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–26748 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–19–M

CDC Advisory Committee on HIV and STD Prevention Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: CDC Advisory Committee on HIV and STD Prevention.

Times and Dates: 9 a.m.–5 p.m., November 12, 1996. 9 a.m.–1 p.m., November 13, 1996.

Place: Corporate Square Office Park, Corporate Square Boulevard, Building 11, Room 1413, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This committee is charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV and STD prevention efforts including maintaining surveillance of HIV infection, AIDS, and STDs, the epidemiologic and laboratory study of HIV/AIDS and STDs, information/education and risk reduction activities designed to prevent the spread of HIV and STDs, and other preventive measures that become available.

Matters to be Discussed: Agenda items will include an overview of HIV and STD divisions and the Prevention Services Office; updates on prevention activities related to injecting drug users and persons in correctional facilities, partner notification, lesbian HIV issues, HIV counseling and testing, syphilis elimination, behavioral research and managed care; surveillance on unusual variants of HIV; and an evaluation plan for HIV.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Connie Granoff, Committee Management Specialist, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, Georgia 30333, telephone (404) 639–8029.

Dated: October 11, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–26747 Filed 10–17–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96N–0327]

Use of Formalin Solution on All Finfish; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of target animal safety and effectiveness data, human food safety data, and environmental data to be used in support of a new animal drug application (NADA) or supplemental NADA for control of certain external protozoa and monogenetic trematodes on all finfish and certain fungi on the eggs of all finfish through water treatment with formalin solution. The data, contained in Public Master File (PMF) 5228, were compiled under National Research Support Project No. 7 (NRSP–7), a national agricultural program for obtaining clearances for use of new drugs in minor animal species or in any animal species for the control of diseases that occur infrequently or in limited geographical areas.

ADDRESSES: Submit NADA's or supplemental NADA's to the Document

Control Unit (HFV–199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–3125.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: The use of formalin solution on finfish is a new animal drug use 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, formalin solution is subject to section 512 of the act (21 U.S.C. 360b), which requires that its use on finfish be the subject of an approved NADA or supplemental NADA. Finfish are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

Formalin solution is currently approved for control of: (1) Certain external, protozoan parasites and monogenetic trematodes on salmon, trout, catfish, largemouth bass, and bluegill; and (2) fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs in accordance with 21 CFR 529.1030. The NRSP–7 Project, Southern and Western Regions (University of Florida, Gainesville, Florida and University of California, Davis, California), has filed data and information that demonstrate safety and effectiveness to all other finfish when they are administered formalin solution for the above mentioned conditions of use. NRSP–7 has also filed human food safety data and an environmental assessment (EA), amended by the Center for Veterinary Medicine, that adequately addresses the potential impacts due to the expanded use of the drug product. Approval of an application based on the data and information in this file requires additional information concerning the potential environmental impact of the manufacturing process. The abbreviated EA will be displayed when the NADA is approved, so that the manufacturing site environmental impact can be included in the assessment. The EA filed by NRSP–7 may be seen at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The data and information are contained in PMF 5228. Sponsors of NADA's or supplemental NADA's may, without further authorization, refer to the PMF to support approval of an application filed under § 514.1(d) (21 CFR 514.1(d)). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other data needed for approval, such as manufacturing methods, facilities, and controls, and information addressing the potential environmental impacts (including occupational) of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Naba K. Das (address above).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and 21 CFR 514.11(e)(2)(ii), a summary of target animal safety, effectiveness, and human safety data and information provided in this PMF to support approval of an application may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 7, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–26682 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0255]

CareLink Corp.; Premarket Approval of CareFone™ Home Uterine Activity Monitoring System, Model 2001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CareLink Corp., Santa Ana, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of CareFone™ Home Uterine Activity Monitoring System, Model 2001. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by November 18, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION: On December 23, 1991, CareLink Corp., Santa Ana, CA 92705, submitted to CDRH an application for premarket approval of CareFone™ Home Uterine Activity Monitoring System, Model 2001. The device is a home uterine activity monitor and is indicated for use in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On September 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition,