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,

FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 18, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 4, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–26683 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the National Mammography Quality Assurance Advisory Committee, which is scheduled for October 21, 22, and 23, 1996. This meeting was announced in the Federal Register of September 24, 1996 (61 FR 50031 at 50033). The amendment is being made to add a closed session to the agenda scheduled for October 23, 1996. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 24, 1996, FDA announced that a meeting of the National Mammography Quality Assurance Advisory Committee would be held on October 21, 22, and 23, 1996.

On page 50033, in the first column, the ''*Type of meeting and contact person*'' portion is amended as follows:

Type of meeting and contact person. Open public hearing, October 21, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, October 22, 1996, 9 a.m. to 5 p.m.; open committee discussion, October 23, 1996, 8 a.m. to 10 a.m.; closed committee deliberations, 10 a.m. to 10:30 a.m.; open committee discussion, 10:30 a.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.

On page 50033, in the second column, in addition to the open committee discussion of the request of the American Board of Certification in Radiology to be designated as eligible to certify interpreting physicians under the Mammography Quality Standards Act (the MQSA), a ''*Closed committee deliberations*'' portion is added as follows:

Closed committee deliberations. On October 23, 1996, the committee will discuss confidential commercial information submitted in connection with the request of the American Board of Certification in Radiology to be designated as eligible to certify interpreting physicians under the MQSA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act