Summary

To advance human health, it is critical that human biological materials continue to be available to the biomedical research community. Increasingly, it will be essential for investigators to collect human biological materials from individuals who are willing to share important clinical information about themselves. In addition, it is crucial that the more than 282 million specimens already in storage remain accessible under appropriate conditions and with appropriate protections for the individuals who supplied this material.

The growing availability to third parties of genetic and other medical information about individuals has fueled the current debate about medical privacy and discrimination, and NBAC is sensitive to the possibility that the use of information obtained from human biological samples can lead to harms as well as benefits. These concerns require that those who agree to provide their DNA, cells, tissues, or organs for research purposes not be placed at risk. Measures to provide appropriate protections for individual privacy and for the confidentiality of clinical and research data are important if significant research is to continue. The recommendations provided in this report are intended to promote the goals of improving health through biomedical research while protecting the rights and welfare of those individuals who contribute to human knowledge through the gift of their biological materials.

For further information about the report contact Eric M. Meslin, Ph.D., Executive Director, National Bioethics Advisory Commission or to obtain copies of the report contact: Ms. Patricia Norris, National Bioethics Advisory Commission, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892–7508, telephone 301–402–4242, fax number 301–480–6900. Copies may also be obtained through the NBAC website: www.bioethics.gov.

Dated: September 27, 1999.

Eric M. Meslin,

Executive Director, National Bioethics Advisory Commission.

[FR Doc. 99–25663 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0240]

Agency Information Collection Activities; Announcement of OMB Approval; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Extralabel Drug Use in Animals'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 30, 1999 (64 FR 35173), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0325. The approval expires on September 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25774 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of September 22, 1999 (64 FR 51328). The notice announced a meeting of the Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee), which is scheduled for October 14 and 15, 1999. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Ronald F. Coene, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696.

SUPPLEMENTARY INFORMATION: In FR Doc. 99–24598 appearing in the **Federal Register** of Wednesday, September 22, 1999, the following correction is made:

On page 51328, in the second column, under the ''*Location*'' caption, in the second line ''rm. K'' is corrected to read ''rm. M''.

Dated: September 28, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–25772 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4003]

Medical Devices; Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses.'' This draft guidance is not final nor is it in effect at this time. The purpose of this document is to provide guidance to sponsors of breast implant prostheses on important preclinical, clinical, and labeling information that should be presented in an investigational device exemptions (IDE), a premarket approval (PMA), or a product development protocol (PDP) application. This draft guidance discusses information relevant to silicone gel-filled, saline-filled, and alternative-filled breast prostheses intended for prostheses for breast augmentation, breast reconstruction

following mastectomy, and revision of a failed prosthesis.

DATES: Written comments concerning this draft guidance must be received by January 4, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samie N. Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide guidance to sponsors of breast implant prostheses on important preclinical, clinical, and labeling information that should be presented in an IDE, PMA, or PDP application. It may also be useful in the preparation of reclassification petitions and master files.

This draft guidance discusses information relevant to silicone gel-filled, saline-filled, and alternative-filled breast prostheses intended for prostheses for breast augmentation, breast reconstruction following mastectomy, and revision of a failed prosthesis. This draft guidance does not address tissue expanders, which are unclassified devices for temporary use. Additionally, this draft guidance does not address alternative shell materials for use in breast implants.

This draft guidance is intended to combine and replace the following three individual guidances that were previously developed for silicone gel, saline, and alternative breast prostheses:

(1) ''Draft Guidance for Preparation of FDA Submissions of Silicone Gel–Filled Breast Prostheses'' (May 11, 1992); (2) ''Draft Guidance for Testing of Alternative Breast Prostheses (Non–Silicone, Gel–Filled)'' (September 1, 1994); and (3) ''Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses'' (January 18, 1995).

In addition, this draft guidance involves the revisiting and updating of the scientific preclinical and the clinical and labeling information described in those guidances.

II. Significance of Guidance

This guidance document represents the agency's current thinking on preclinical, clinical, and labeling information for breast prostheses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance document consistent with GGP's.

III. Electronic Access

In order to receive the ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1354) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' also will be available at http://www.fda.gov/cdrh/ode/1354.pdf.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1999.

Linda S. Kahan,

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

[FR Doc. 99–25771 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9042]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Accelerated Payments and Supporting Regulations in 42 CFR, Section 412.116 & 413.64;

Form No.: HCFA–9042;