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