hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug products. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Thompson, D., and G. Oster, ''Use of Terfenadine and Contraindicated Drugs,'' *Journal of the American Medical Association,* 275(17):1339–1341, 1996.

2. Cavuto, N. J., R. L. Woosley, and M. Sale, ''Pharmacies and Prevention of Potentially Fatal Drug Interactions'' (letter), *Journal of the American Medical Association,* 275(14):1086–1087, 1996.

3. Carlson, A. M., and L. S. Morris, ''Coprescription of Terfenadine and Erythromycin and Ketoconazole: An Assessment of Potential Harm,'' *Journal of the American Pharmaceutical Association,* NS36(4):263–269, 1996.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: January 7, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–714 Filed 1–10–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Consensus Development Conference on Breast Cancer Screening For Women Ages 40–49

Notice is hereby given of the NIH Consensus Development Conference on ''Breast Cancer Screening For Women Ages 40–49,'' which will be held January 21–23, 1997, in the Natcher Conference Center of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on January 21, at 8 a.m. on January 22, and at 9 a.m. on January 23.

A number of randomized clinical trials have shown clearly that early detection of breast cancer by mammography, with and without clinical breast examination at regular intervals ranging from 1 year to 33 months, reduces breast cancer mortality in women ages 50–69 by about a third. However, the picture is not as clear for women 40–49 years of age, and worldwide experts continue to examine the data regarding the use of mammography in this age group. Follow-up data from the Swedish, Canadian, Edinburgh (U.K.), and health Insurance Plan of New York clinical trials will be presented at the conference in an attempt to help clarify these issues.

This conference will bring together the investigators who have conducted the randomized clinical trials, epidemiologists, statisticians, radiologists, oncologists, and other experts, as well as representatives of the public, to present and discuss the latest data and data analyses.

After 1½ days of presentations and audience discussion, an independent, no-Federal consensus panel will weigh the scientific evidence and write a draft statement that it will present to the audience on the third day. The consensus statement will address the following key questions:

—Is there a reduction in mortality from breast cancer due to screening women ages 40 to 49 with mammography, with or without physical examination? If so, how large is the benefit? How does it change with age?

—What are the risks associated with screening women ages 40–49 with mammography and with physical examination?

Are there other benefits? If so, what are they? How do they change with age?

—What is known about how the benefits and risks of breast cancer screening differ based on known risk factors for breast cancer?

—What are the directions for future research?

The primary sponsors of this conference are the National Cancer Institute and the NIH Office of Medical Applications Research. The conference is cosponsored by the National Institute on Aging, the NIH Office of Research on Women's Health, and the Centers for Disease Control and Prevention.

Advance information on the conference program and conference registration materials may be obtained from Hope Levy Cott, Technical Resources International, Inc., 3202 Tower Oaks Blvd., Suite 200, Rockville, Maryland 20852, (301) 770–3153, or by sending e-mail to confdept@tech-res.com.

The consensus statement will be submitted for publication in professional journals and other publications. In addition, the statement will be available beginning January 23, 1997, from the NIH Consensus Program Information Center, P.O. Box 2577, Kensington, Maryland 20891, phone 1–888–NIH–CONSENSUS (1–888–644–2667), and from the NIH Consensus Development Program site on the World Wide Web at http://consensus.nih.gov.

Dated: January 7, 1997.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 97–850 Filed 1–13–97; 8:45 am]

BILLING CODE 4140–01–M

John E. Fogarty International Center for Advanced Study in the Health Sciences; Notice of Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92–463, as amended, notice is hereby given of the thirty-fifth meeting of the Fogarty International Center (FIC) Advisory Board, February 4, 1997, in the Lawton Chiles International House (Building 16) at the National Institute of Health.

The meeting will be open to the public from 8:30 a.m. to 12:00 p.m.

The agenda will include a report by the Director, FIC; a report on the Recommendations of the External Advisory Panel to Review NIH/FIC International Programs followed by a discussion of the recommendations led by the Director, NIH; a report on the December Meeting of the Advisory Committee to the Director, NIH; a presentation on the recommendations of a review panel on the FIC AIDS International Training and Research Program; and a report on the International Conference on Malaria that