Prevention (CDC), announces the following committee meeting.

Name: NCVHS Executive Subcommittee.

Times and Dates: 9 a.m.–5 p.m., August 29, 1995, 9 a.m.–2 p.m., August 30, 1995.

Place: The Bavarian Inn, Route 1, Shepherdstown, West Virginia 25443.

Status: Open.

Purpose: The purpose of this meeting is for the Executive Subcommittee to review accomplishments, structure, needs and work plans of NCVHS and individual subcommittees.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: July 25, 1995.

Carolyn J. Russell,

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

[FR Doc. 95–18839 Filed 7–31–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0185]

Drug Export; Arimidex (Anastrozole) 1 Milligram (mg) Tablet

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 June 29, 1995 (60 FR 33810). The document announced that Zeneca Pharmaceuticals Inc., was requesting conditional approval for export of the human drug Arimidex (Anastrozole) 1 mg tablet to the United Kingdom. The document contained an error in indication for use. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

SUPPLEMENTARY INFORMATION: In FR Doc. 95–15969 appearing on page 33810 in the **Federal Register** of Thursday, June 29, 1995, the following correction is made:

On page 33810, in the second column, under the heading **SUPPLEMENTARY INFORMATION**, line 29, the word ''colorectal'' is corrected to read ''breast''.

Dated: July 24, 1995.

Betty L. Jones,

Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–18747 Filed 7–31–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0230]

Statement Regarding the Demonstrations of Effectiveness of Human Drug Products and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its position regarding demonstrations of product effectiveness in new drug applications (NDA's) and premarket approval applications (PMA's). In evaluating NDA's and PMA's, FDA weighs the product's demonstrated effectiveness against its risks and considers other factors such as the seriousness and outcome of the disease being treated and the adequacy of existing treatments. The agency does not require new human drug products or medical devices to be more effective than existing therapies nor does it necessarily require the product to be compared to other products. However, for products intended to treat life-threatening diseases, diseases with irreversible morbidity, and contagious diseases that pose serious health risks to others, it is essential for public health protection that a new therapy be as effective as existing, approved therapies.

DATES: Written comments by October 30, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2831.

SUPPLEMENTARY INFORMATION: On March 4, 1995, President Clinton announced plans for reforming the Federal regulatory system as part of his ''Reinventing Government'' initiative. Part of this reform is aimed at reviewing regulatory processes to determine which requirements could be reduced or eliminated without lowering health and safety standards.

Pursuant to the President's ''Reinventing Government'' initiative, FDA made several recommendations with respect to the regulation of human drug products and medical devices. One recommendation was the issuance of a public statement clarifying certain aspects of the standards for the effectiveness of human drug products and medical devices.

The Federal Food, Drug, and Cosmetic Act (the act) requires NDA's and PMA's to contain full reports of information demonstrating that the drug or device is safe and effective under conditions of use in the product's proposed labeling. (See sections 505(b) and 515(c) of the act (21 U.S.C. 355(b) and 360e(c)).) The agency must deny approval of a NDA or a PMA if it finds that the application does not demonstrate that the product is safe and effective for the uses indicated in the product's proposed labeling. (See sections 505 (c) and (d) and 515(d) of the act.)

Pharmaceutical and device manufacturers have sometimes claimed that the agency requires new human drug products and especially class III devices (devices for which insufficient information exists to assure that general controls and special controls provide reasonable assurance of safety and effectiveness; in general, these are the higher risk devices) to be more effective for their intended uses than comparable therapies that are already approved for marketing. These firms assert that FDA's requirements for demonstrating effectiveness present unreasonable difficulties in developing new therapies and bringing those new therapies to market.

This notice is intended to address the concerns about a comparative effectiveness standard that have been raised. In evaluating the safety of a new drug or medical device, FDA weighs the product's demonstrated effectiveness against its risks to determine whether the benefits outweigh the risks. This weighing process also takes into account information such as the seriousness and outcome of the disease, the presence and adequacy of existing treatments, and adverse reaction and other safety data.

In evaluating effectiveness, FDA reviews new drug products and devices on their merits. FDA does not require new drug products or devices to be more effective than approved therapies for the same disease or condition. In general, both new drug products and class III devices must be shown to be effective through evidence consisting of clinical investigations that provide a basis on which it can be concluded that the new drug product or class III device will be safe and have the effect that it is represented to have.

For most new drug products and new class III devices intended to treat serious