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

illness or provide symptomatic relief, a showing of effectiveness is usually based on a clinical trial comparing the product to a placebo. Such a showing does not necessarily involve a comparison to another active treatment or a product that is known to be effective.

In certain circumstances, however, it may be important to consider whether a new product is less effective than available alternative therapies, when less effectiveness could present a danger to the patient or to the public. For example, it is essential for public health protection that a new therapy be as effective as alternatives that are already approved for marketing when: (1) The disease to be treated is life-threatening or capable of causing irreversible morbidity (e.g., stroke or heart attack); or (2) the disease to be treated is a contagious illness that poses serious consequences to the health of others (e.g., sexually transmitted diseases).

It should be noted that new products are often developed for particular subpopulations who either do not respond to or are not able to tolerate an existing approved therapy. FDA will generally approve for use in such a subpopulation a product that is shown to have effectiveness in this group, regardless of whether the product can be shown to be as effective in the broad target population as the alternative therapy. This is because, in effect, there is no available alternative therapy for the subpopulation. For example, a number of patients cannot tolerate a widely used therapy for an acquired immune deficiency syndrome (AIDS)-related pneumonia. FDA approved atovaquone for use in these patients even though the drug had been shown to be less effective than the standard therapy when tested in a broad population.

An additional issue related to product effectiveness concerns the assertion, by some industry officials, that the act not be interpreted as requiring multiple clinical studies when one ''pivotal'' study could suffice.

FDA believes good science dictates that a showing of effectiveness must be methodologically sound and provide a high level of confidence in the validity of the result. For human drug products, this ordinarily is achieved by independently replicating the result in a second study, to constitute an adequate demonstration of effectiveness for a new product. While a second study may well be needed to replicate results demonstrated in a first study, in some instances, it is possible to replicate results within one large, well-designed, multi-center study. FDA emphasizes that this approach can be successful only when results are strong. The agency has, in the past, approved new human drug products on the basis of a single, multi-center study. Examples include dornase alfa for the treatment of cystic fibrosis, timolol for treatment of people after a heart attack, and zidovudine for AIDS. A statistically marginal result, even in a very large study, cannot provide convincing evidence without replication.

For medical devices, where the mechanism of action is a result of product design and substantially verified by in vitro performance testing, the agency has routinely relied on single studies evaluated for internal and across-center consistency to provide this high level of confidence in the result.

Dated: July 27, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18877 Filed 7–31–95; 8:45 am]

BILLING CODE 4160–01–F–M

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 58 FR 14214, March 16, 1993) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The Office of the Center Director (OCD), Center for Drug Evaluation and Research (CDER) is being reorganized to enhance CDER's responsiveness to its internal and external customers. The Executive Operations Staff is being established to combine project management, executive secretariat, and program management functions. The functions and staff of the Division of Regulatory Affairs are being transferred from the Office of Compliance to OCD as the Regulatory Affairs Staff.

Under section HF–B, Organization:

1. Delete the subparagraph *Office of the Center Director (HFN1)* under the *Center for Drug Evaluation and Research (HFN),* in its entirety and insert a new subparagraph reading as follows:

Office of the Center Director (HFN1). Promulgates, plans, administers, coordinates, and evaluates overall Center scientific, management, and regulatory programs, plans, and policies.

Provides leadership and direction for all Center activities.

Coordinates and directs the Center management, planning, and evaluation systems to assure optimum utilization of Center manpower, financial resources, and facilities.

Directs Center operations for equal employment activities.

2. Insert a new subparagraph *Executive Operations Staff (HFN11)* under the *Office of the Center Director (HFN1)* reading as follows:

Executive Operations Staff (HFN11). Provides executive secretariat support to the Immediate Office of the Center Director, including coordinating executive and legislative correspondence and activities; managing the preparation and coordination of meetings; and preparing background material, graphics, and other information for meetings, speeches, and presentations.

Provides project management support for Centerwide and Agencywide initiatives to improve the quality and timeliness of regulatory reviews and improve team-based management practices.

Provides management support and advice to senior Center management concerning Center programs, including Center extramural contracts and grants activities.

3. Insert a new subparagraph, *Regulatory Affairs Staff (HFN13),* under the *Office of the Center Director (HFN1)* reading as follows:

Regulatory Affairs Staff (HFN13). Initiates, develops, and reviews regulations, policies, procedures, and guidelines that affect the drug approval process.

Serves as the Center's focal point on regulatory issues providing advice and assistance on such matters as scope, applicability, and intents of the Food, Drug, and Cosmetic Act and other laws, regulations, and policies.

4. Delete the subparagraph, *Office of Compliance (HFND),* under the *Center for Drug Evaluation and Research (HFN)* and insert a new subparagraph reading as follows:

Office of Compliance (HFND). Monitors the quality of marketed drugs through product testing, surveillance, and compliance programs.

Advises the Center Director and other Agency officials on FDA's regulatory responsibilities for drugs.

Develops standards for drug industry practices, including Current Good Manufacturing Practice (CGMP) regulations, and ensures their uniform interpretation.

Directs the Center's bioresearch monitoring program for drug products.