SMG 2130.6

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

SAFETY AND OCCUPATIONAL HEALTH PROGRAMS

NOTICES OF HAZARDOUS OR DANGEROUS EQUIPMENT

Transmittal Number 88-91 -- Date: 07/11/88

1. Purpose
2. Background
3. Policy
4. Responsibilities

1. PURPOSE

To establish policy and identify responsibilities for communicating notices warning of hazards in equipment and other products used by the Food and Drug Administration to the FDA Safety Office, and to provide for the notification of program managers whenever the FDA Safety Office determines that a hazard exists in a product used in the Agency.

2. BACKGROUND

As specific needs arise, GSA, manufacturers of equipment and others issue notices of hazard or warnings of danger to alert users that conditions have been detected that pose safety hazards. New items of equipment may be supplied with warning notices also to prescribe specific procedures for safe use, to prescribe conditions under which danger can be expected, and to describe how a potentially dangerous equipment failure can occur. These warnings may be received in a number of ways:

- By mail on company letterhead which resembles advertising;
- As an identified hazard warning in a special mailing;
- In operating instructions, affixed to the item of equipment;
- As a sheet of instructions enclosed in the shipping container; and
- Delivered in some other manner.

Warnings can be expected for equipment and other products used in FDA's offices, in FDA's laboratories, and in inspection activities. It is important that

copies of these warning notices reach the FDA Safety Office for appropriate distribution in the Agency.

3. POLICY

All notices warning of hazardous, unsafe, or otherwise dangerous equipment or products shall be promptly evaluated by offices of the Commissioner, Center, and ORA safety personnel. The FDA Safety Office is to be apprised of all warning notices received by any FDA component. Any other person within FDA, who should be aware of the warning, shall also be promptly notified.

4. RESPONSIBILITIES

A. Employee Who Receives Warning Notice. Any FDA employee who receives a hazard or danger warning concerning an item of equipment shall promptly notify the supervisor in charge and the designated local safety officer.

B. Supervisors and Safety Officers.

1. The supervisor who is notified of a danger or hazard warning will, with the assistance of the local safety officer, assess the seriousness of the warning. If it is considered that the information should be made available to other FDA components, the FDA Safety Office should be contacted as expeditiously as possible.

2. A copy of each hazard warning, which is considered to apply only at the recipient's facility, should be forwarded to the FDA Safety Office for retention.

3. Any supervisor or safety officer, who wants to know if a notice or other warning of danger has been issued for a particular item of equipment, should contact the FDA Safety Office.

C. FDA Safety Office.

1. The FDA Safety Office will promptly evaluate each hazard/danger warning received and will notify those supervisors, program managers, safety officers, or others who have a need to know if the circumstances warrant.

2. A file of notices warning of hazard and danger will be maintained by the FDA Safety Office.