GENERAL REVIEW AND ENFORCEMENT POLICIES

TYPES OF REGULATORY ACTIONS

1. Purpose:

   This guide describes the types of regulatory actions used by the Food and Drug Administration.

2. Responsibility for Initiating Regulatory Action:

   a. The FDA field offices have the primary responsibility for initiating regulatory action recommendations commensurate with Agency policy and priorities.

   b. All Divisions within the Center are responsible for identifying regulatory problems and making appropriate recommendations to the Office of Surveillance and Compliance.

3. Seizure:

   a. A seizure is an action brought under administrative proceedings against an animal feed, drug, or device which is in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA) for being:

      (1) Adulterated, and/or

      (2) Misbranded

   b. Seizure actions are directed against articles (animal feeds, drugs, or devices) rather than against individuals.

   c. Any person having an interest in the seized article may come forward as a claimant. The claimant may under certain circumstances request that the proceedings be transferred to the Federal Court nearest his/her principal place of business. The manufacturer or distributor, for example, rather than the dealer, may come forward as a claimant.

   d. If no claimant appears, the article may be condemned by the court under terms of a

default decree, and destroyed under the supervision of the Food and Drug Administration.

e. If a claimant appears and contests the seizure, a trial may be held if a consent decree of condemnation is not entered into. If the article is condemned, the claimant may petition the court to release the goods for the purpose of bringing them into compliance, post bond for performance, and recondition the goods under FDA supervision and approval. If the seizure is contested, the Food and Drug Administration must produce evidence, including proof of the interstate shipment of the article or its components, to support the allegations made in the libel of information. FDA employees may testify, but in many cases, outside experts in the appropriate fields are secured to testify as to the lack of general recognition of safety and effectiveness (new animal drug) or other technical aspects, such as to the significance of failure to comply with GMP requirements.

f. If a decree of condemnation is entered (either after trial or by consent), the court may direct disposition of the article by:

(1) Destruction in accord with a court decree. This may include physically destroying the merchandise by burying or incinerating, or only allowing it to be utilized for a purpose not falling under the purview of the Act, such as for fertilizer, or

(2) Reconditioning. (Under the supervision and approval of the Food and Drug Administration.)

g. Once a decision has been rendered, it may become established precedent for both the Food and Drug Administration and the regulated industry. Court decisions may be appealed to and reversed or affirmed by a Court of Appeals or the Supreme Court.

h. Multiple seizures may be taken of adulterated goods. However, multiple seizures for misbranding may not be taken if there is already a seizure action pending for the same violation, except that this limitation shall not apply:

(1) When such misbranding has been the basis for a prior judgment in favor of the government, or
(2) If there is cause to believe that the misbranded article is dangerous to health, or the labeling is fraudulent or would in material respect misleading to the

injury or damage of the consumer purchaser.

4. Injunction:

   a. An injunction is a writ granted by a court whereby one is required to do or refrain from doing a specified act. In most instances FDA seeks injunctions against individuals and corporations to prevent them from violating or causing violations of the Act.

   b. An injunction is obtained by filing a complaint and requesting a hearing before the appropriate Federal Court. FDA ordinarily presents expert testimony to prove that the action complained of is a violation or is causing a violation and that there is reason for the parties to be restrained. The defendant is allowed to present testimony to refute the charges and demonstrate that the article or activity is not violative. The court then hands down a decision, either granting or denying the injunction. In some situations the court may issue a temporary restraining order and grant an expedited hearing when immediate public protection is needed.

   c. If an injunction is granted and violations continue to occur, the defendant may be brought back before the court in a contempt action. This may only require evidence by the government that the enjoined has defied the court order.

   d. In some cases, the individual or firm may fail to adequately comply with the terms of the injunction due to an inadequate understanding of the terms, or due to other reasons which do not warrant a contempt action. In such cases an appropriate action may be to ask the court to reaffirm the original injunction or modify it to facilitate compliance.

5. Criminal Prosecution:

   a. Section 301 of the FFDCA lists certain actions which are prohibited. Any person who violates these provisions is subject to criminal prosecution by the government.

   b. A section 305 notice is ordinarily issued before recommending prosecution. The law provides that persons alleged to have caused violations shall be given an opportunity to present their views before actual criminal charges are filed. A Notice of Meeting is prepared, detailing the violations and the manner in which the accused is alleged to be responsible for their occurrence. The individual(s) may choose to be non-

responsive, may respond in writing, may appear in person, or may be represented by someone else at the scheduled meeting, usually held at the local District Office. He/she may bring legal counsel and be given opportunity to explain and present evidence why he/she should not be prosecuted. The meeting is informal and held only to allow the accused to present their views. Cross-examination or discovery type questioning is not deemed appropriate. The Center must approve the holding of a Section 305 meeting.

c. Proceeding with prosection. If prosecution is deemed appropriate following the Section 305 meeting, a recommendation is then forwarded to the Division of Compliance Management Operations, Office of Enforcement, if the Section 305 meeting did not produce any significant facts changing the character or nature of the case. Otherwise, it is transmitted to the Center for review and decision. If approved, the case is forwarded to the Office of Enforcement, then to the office of the general counsel and then to the Justice Department for review and filing in the appropriate District Court by the U.S. attorney. The case may be tried by a judge or by jury. In criminal prosecutions, expert testimony together with extensive testimony from fact witnesses, such as FDA investigators and analysts is ordinarily needed to support the government's allegation.

6. Recall:

a. The most effective method of protecting the consumer from illegal products is prompt total removal from the market or correction, either as initiated by the distributor or following a request from the Associate Commissioner for Regulatory Affairs.

b. Procedures for implementing a recall are described in CVM Program Policy and Procedures Manual - 1240.3540 and the Regulatory Procedures Manual. The regulations pertaining to recalls appear in 21 CFR 7.40 - 7.59.

NOTE: There is no statutory authority for recalls. All recalls are therefore voluntary on the part of the recalling firm. However, recalls are normally identified as "firm-initiated" or as "FDA-initiated." In the latter case, the recall is initiated by the firm at the request of the Associate Commissioner for Regulatory Affairs.