

CPG Sec. 448.100 Reconditioning of New Drugs Which Do Not Have Approved NDAs/ANDAs

BACKGROUND:

Prior policy under the DESI program permitted the marketing of new drugs evaluated as effective upon the submission of a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). This policy was challenged and overturned in a decision handed down on July 29, 1975, by the U.S. District Court for the District of Columbia (Hoffman La Roche vs. Caspar Weinberger, et al). The Agency implemented this order (Judge Green's decision) through Compliance Program 7332.26 covering products identical or related ("me too" drugs) to DESI drugs identified in a list published 1/76 (DHEW publication No. (FDA) 76-3009).

Agency policy as set forth in the program required that such new drugs be discontinued from marketing and recalled if substantial stocks remain in trade channels. When responsible firms have failed to initiate the above actions after being warned by issuance of a *warning letter*, unapproved new drugs have been seized.

Although recall or seizure may have been necessary for uniform enforcement and protection of the public health, destruction of such recalled or seized material is not always required provided adequate safeguards are taken.

POLICY:

In those instances in which an Abbreviated New Drug Application has been submitted and is currently pending, we will not insist upon destruction of recalled or seized material resulting from implementation of Compliance Policy Guide 7132c.02 involving DESI effective drugs provided:

1. Recalled stocks are quarantined by the formulator and not held by consignees, i.e., substantial stocks in the hands of consignees must be disposed of either by return to the formulator or by destruction. Failure to do so will result in recommendation for regulatory action by the appropriate division within the Office of Pharmaceutical Quality Operations (OPQO), preferably seizure.
2. Recalled (quarantined lots at the formulator) or seized material may not be released until and unless all the following conditions are met:
 - A. Approval of an NDA or ANDA is received.
 - B. The firm can validate that the lots in question were manufactured in accordance with the specifications of the approved NDA/ANDA including the following:
 1. Compliance with CGMP.
 2. Affected lots meet all purity, potency and labeling standards specified by the approved NDA/ANDA.

3. Where an unapproved new drug has been seized, under either Section 505 or 502, and as a result of subsequent ANDA approval it is not in the public interest that it be condemned and destroyed under Section 304(d)(1), the Agency may consider entering into a stipulation of dismissal incorporating the following principles:
 - a. The claimant shall assure the Agency, by way of appropriate records, that the drug is in full compliance with the approved ANDA prior to dismissal of the complaint.
 - b. Where consistency with the approved ANDA requires labeling modifications, and compliance cannot be assured by a records review as in *"a."* above, the Court may order the seized article be remanded to the custody of the claimant for the sole purpose of making the required modifications. If and when the Agency is satisfied that the required modifications have been made, and the article is in all respects consistent with the approved ANDA, the complaint may be dismissed.
 - c. All activity undertaken to assure that the seized article is in compliance with the law shall be at the expense of the claimant, including investigatory and laboratory work performed by Agency personnel. Current fee and mileage schedules shall apply, and payment shall be received prior to dismissal of the action and full release of the article.

Where no NDA/ANDA has been submitted, or if the appropriate division within OPQO has information that quarantined or seized lots will not meet the above conditions or approval of a current pending application does not appear probable within a reasonable time frame (three months), then we will insist upon destruction of stocks. In the case of the latter, concurrence by Division of Drug Labeling Compliance (HFD-310) is required.

Except upon the specific conditions outlined above, nothing in these provisions shall be construed as altering Agency policy that articles seized pursuant to Section 304 may not be reconditioned by Agency consent without the entry of a decree condemning the articles and providing for reconditioning under Agency supervision.

Material between asterisks is new or revised

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