



JUL 23 1991

Dear Sir or Madam:

This is the eighth in a series of policy letters regarding the implementation of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA), which was signed into law on November 16, 1988.

The purpose of this letter is to announce the Center for Veterinary Medicine's policy with regard to the generic copying of certain drugs that were subject to review under the Drug Efficacy Study Implementation (DESI) program. Briefly, the policy is that CVM will not permit copying of a DESI-reviewed drug product unless that product has been "DESI-finalized," i.e., the Agency has approved the drug product for effectiveness and its labeling complies with the conditions of that approval.

In connection with this policy determination, the agency is removing certain "nonfinalized" DESI-reviewed New Animal Drug Applications (NADA's) from the list of drug products that are eligible for copying under GADPTRA, and is placing the NADA's in a separate list. The change will be reflected in an upcoming 1991 monthly supplement to FDA Approved Animal Drug Products (the Green Book*).

The DESI Program

Under the DESI program, NADA's approved prior to October 10, 1962 were reviewed to determine the drugs' effectiveness for labeled claims. (Drugs whose applications had become effective prior to that date had been reviewed only for safety.) Some of the DESI-reviewed drugs were found to be effective for one or more indications; typically, however, the DESI review required labeling changes for those drugs. Other drugs were found to be less than effective; in most cases, sponsors of products containing those drugs were required to submit additional data to establish the effectiveness of their drug products.

Some sponsors complied with the requirements of the DESI notices, and DESI-approved claims for such drug products are codified in 21 CFR parts 520 et seq as documentation of FDA's approval for effectiveness. However, other sponsors did not comply; although approvals of many of the affected NADA's have been withdrawn, final action has not yet been taken on approximately 34 NADA's. Some of these nonfinalized drugs were rated effective for certain claims, but their sponsors have not submitted revised labeling to comply with the notice. Other drugs were rated less than effective for all claims. The nonfinalized NADA's and the change in the Green Book listings are the subjects of this policy letter.

The GADPTRA List

Under GADPTRA, FDA "lists" a drug product, i.e., the drug product is eligible for copying, if that drug product has been approved both for safety and effectiveness. CVM has tentatively concluded that a DESI-reviewed NADA may not be listed unless FDA has approved the drug product for effectiveness, i.e., the sponsor has complied fully with the DESI requirements and that compliance is reflected in the approved NADA. Thus, even if the DESI review concluded that the drug product was effective for one or more

indications, the drug may not be listed until the sponsor has made any required changes (e.g., in labeling) and those changes have become the subject of an approved supplemental NADA.

The NADA's that are the subject of this letter were included in the Green Book list of drugs eligible for copying when the Agency first published the list. However, the Agency also stated at the time that it published the list that CVM was reviewing certain drugs approved prior to 1962 to determine whether any should be removed from the list [54 FR 6608 (February 13, 1989)]. Moreover, in our seventh GADPTRA policy letter (March 20, 1991), CVM stated that DESI-reviewed subtherapeutic drugs containing penicillin and the tetracyclines could be copied under GADPTRA only if they had been approved for effectiveness as well as safety [56 FR 15083 (April 15, 1991)].

Although the Agency is removing the nonfinalized drug products from the list of drugs that have been approved for safety and effectiveness, it will for convenience maintain a separate list of these NADA's in the Green Book. NADA's that are brought into compliance with the DESI review will be returned to the original list, and NADA's whose approvals are withdrawn will simply be removed from the supplemental list.

Conclusions

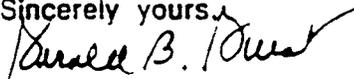
CVM recognizes that the policy decision announced in this letter will preclude approval of applications to copy the drug products in question, even though the pioneer sponsors may continue to market their products for the time being. Accordingly, the Center is taking action, as rapidly as its resources will allow, to withdraw approval of the pioneer NADA's whose sponsors do not comply with the applicable DESI requirements.

CVM acknowledges that it may not have identified all the pre-62 drugs that have not complied with the requirements of the DESI program. Similarly, there may be pre-62 NADA's that are not included in either the regular or supplemental lists in the Green Book and that will need to be reviewed for compliance with the DESI program. We welcome suggestions for corrections to either list, as well as comments and questions regarding the statement of policy contained in this letter.

If any changes are made in CVM policy on the nonfinalized DESI drugs, the revised statement will be placed on public display, and a notice of availability will be published in the FEDERAL REGISTER. Comments on any of the GADPTRA policy statements may be submitted to Docket Number 88N-0394, at the following address:
Dockets Management Branch, HFA-305, Park Building Room 1-23, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20857.

We will continue to announce the availability of future policy statements regarding implementation of GADPTRA.

Sincerely yours,



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Director, Center for
Veterinary Medicine