CENTER FOR DRUG EVALUATION AND RESEARCH

Guidance for Industry

The FDA published Good Guidance Practices in February 1997. This guidance was developed and issued prior to that date.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 1 1985

Dear Sir or Madam:

This is the third in a series of letters intended to inform you of policy and procedure developments with respect to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984 amending the Federal Food, Drug, and Cosmetic Act (the Act).

I have enclosed a copy of my letter to the Pharmaceutical Manufacturers Association (PMA) responding to a letter PMA sent the agency. My letter contains the agency's current position on several issues arising under the new legislation, including a change in the Agency's position on the publication of formulation and composition patents. I would like to share with you some of our thoughts regarding this change in our policy, and the resulting impact on other sections of the amended Act.

The agency initially interpreted amended section 505 of the Act to require publication only of use patents for new indications and drug patents for the active ingredients. After careful consideration and reevaluation, however, we have concluded that, as the PMA had stated, the publication requirement includes formulation and composition patents that claim a listed drug product. Process patents are excluded specifically and have not been and will not be published by the agency.

Publication of formulation and composition patents is important because any firm wishing to submit an ANDA or paper NDA for a listed drug must make a certification with respect to each patent published by the Agency. The Agency anticipates a substantial increase in the number of such certifications as a result the publication of formulation and composition patents.

A patent that claims a drug, unlike a patent that claims a use, must refer to an approved drug product. To ensure that only appropriate patents are published, the Agency is asking all holders of approved applications, whether or not they previously submitted information on composition or formulation patents, to submit or resubmit such information with the following statement: "The undersigned certifies that the drug and the formulation or composition of such drug claimed by the following patents are currently approved under section 505 of the Federal Food, Drug and Cosmetic Act." The certification must be signed by the patent holder or by the person responsible for the NDA submission. The Agency intends to publish this additional patent information in its next supplement to the Approved Drug Products List after the information with the above-described certification is received.

Sincerely yours,

Harry M. Meyer, Jr.
Director
Center for Drugs and Biologics

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratic
Rockville MD 20857

Gerald J. Mossinghoff, President
and
C. Joseph Stetler
Pharmaceutical Manufacturers Association
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

MAR 26 1985

Dear Messrs. Mossinghoff and Stetler:

Thank you for your letter of December 20, 1984, sharing with us and inviting our comments upon the PMA's interpretation of a number of provisions of the Drug Price Competition and Patent Term Restoration Act (the Act). We have carefully considered your letter and have the following comments.

Antibiotics

While we understand the rationale behind your assertion that antibiotics should be included in the implementation of Title I of the Act, we disagree with your interpretation of the Act for the following reasons. Title I of the Act specifically refers to new drug applications submitted under Section 505 of the Federal Food, Drug, and Cosmetic Act (FDC Act), but does not refer to Section 507 of the FDC Act. In fact, neither Title I of the Act nor its legislative history refers to antibiotics. As you have pointed out, Title II of the same statute does refer specifically to antibiotics. Thus, had the drafters intended to include antibiotics in the provisions of Title I, it appears reasonable to conclude that they would have referred to them in Title I.

The drafters of the legislation were aware that under Section 507 of the FDC Act, procedures have existed for many years by which generic antibiotic drugs can be approved without duplicating the innovator's safety or effectiveness data. Because the intent of Title I was to provide a similar mechanism for other drugs, the omission of antibiotics from its provisions would seem to be the result of a desire by the drafters not to disturb already existing generic antibiotic drug provisions.

You are correct that FDA regulations, promulgated before the passage of the Act, asserted that antibiotic drug products, exempt from certification, are also new drugs under Section 505. However, those regulations also provide that antibiotics, including generic copies, are to continue to be evaluated and approved under Section 507.

Pending Paper NDAs

The agency's interpretation of the Act not to require sponsors of paper NDAs pending at the time of enactment to amend their applications to conform with the new patent provisions stems from the rationale that such applications were not created by, but rather existed prior to, the new legislation. To add requirements and paperwork for both the industry and FDA to fit those applications to the new requirements would not be in keeping with sound legal and regulatory policy. These applications were legally submitted

before the date of enactment and met the requirements for submission existing at that time. Certainly the innovators would not normally have expected patent certification and notification from paper NDA applicants before September 24, 1984. Therefore, the agency has concluded that as long as those paper NDAs retain their original character, that is, as long as they are not converted to post-1962 ANDAs, we will not require them to comply with the certification provisions of the new statute.

Further, Section 103(a) of the new Act requires that a patent certification be included in paper NDAs "submitted under paragraph (1)" of amended Section 505(b) of the FDC Act. In FDA's view, paper NDAs submitted prior to enactment of the new law are not applications "submitted under paragraph (1)" because no paragraph (1) existed in Section 505(b) at the time of their submission. Such applications are therefore not subject to the certification requirement.

With respect to your comment that Section 103(b)(3)(D) of the Act specifies that the Secretary may not make the approval of a paper NDA effective before the expiration of a certain number of years, we agree that this section applies equally to applications submitted before and after enactment of the legislation. The legislation prohibits the Secretary from approving certain applications after September 25, 1984. These latter provisions, prohibiting approval of paper NDAs for varying periods, are quite different from those provisions of the Act that specify the required contents of an ANDA or paper NDA at the time they are submitted.

Formulation and Composition Patents

The agency has reconsidered its determination that patents claiming a formulation of an approved drug are not covered by the provisions of the Act. The agency has concluded that drug composition patents, including formulation patents, are covered by the provisions of the Act that require the filing "... of any patent which claims the drug for which the applicant submitted the application." The agency, therefore, intends to publish composition patents, including formulation patents, claiming the drug for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted in the event of unlicensed manufacture, use or sale of the drug.

Sincerely yours,

Harry M. Meyer, Jr., M.D.
Director
Center for Drugs and Biologics