PHARMACEUTICAL SCIENCES

REQUESTS FOR EXPEDITED REVIEW OF SUPPLEMENTS TO APPROVED ANDA'S AND AADA'S

CONTENTS

PURPOSE

- To revise the Office of Generic Drugs' (OGD) policy and procedure (Policy and Procedure Guide #18-90, dated March 29, 1990) relating to requests for expedited review of supplements[1] to abbreviated new drug applications (ANDA's) and abbreviated antibiotic applications (AADA's).

BACKGROUND

- The regulations, 21 CFR 314.70(b), provide that: "An applicant may **ask** (emphasis supplied) FDA to expedite its review of a supplement if a delay in making the change described in it would impose an extraordinary hardship on the applicant." The applicant is instructed to mark its supplement and mailing cover: "Supplement - Expedited Review Requested."

- In the past, the Office has been liberal in responding to requests for expedited review to comply with the spirit of the Waxman-Hatch legislation - to bring low-cost/high-quality generic drugs to the marketplace expeditiously. OGD has found, however, that requests for expedited review place a strain on already scarce review resources, and has, therefore, decided to limited expedited reviews to supplements which would accomplish a public health need, eliminate an extraordinary hardship on the applicant, or accomplish a bona fide Agency goal.

POLICY AND PROCEDURE

- Requests for expedited review will be considered on a case-by-case basis, and will be undertaken if adequate review resources are available. Consideration for expedited review will be given only when the basis for the request is clearly stated by the applicant and sufficient supporting documentation is included.

  1. Criteria for Granting Expedited Reviews

Expedited review may be warranted if the supplement relates to:

a. Public health need. Events that affect the availability of a drug for which there is no alternative.

b. Extraordinary hardship on the applicant.

(1) Catastrophic events such as explosion, fire, storm damage.

(2) Events that could not have been reasonably foreseen, and for which the applicant could not plan. Examples include:

(i) abrupt discontinuation of supply of active ingredient, packaging material, or container closure.

(ii) relocation of a facility or change in an existing facility because of a catastrophic event [see item 1.b.(1)]. (Otherwise, the applicant should submit its supplement early in the planning stage of a contemplated relocation/change for routine review.)

c. Agency need.

(1) Matters regarding the government's drug purchase program, upon request from the appropriate FDA office. The Office reserves the right to expedite review without a request in this case as well as the one described in item c.(2) below.

(2) Federal or state legal/regulatory actions, including mandated formulation changes or labeling changes if it is in the Agency's best interest.

This does not include actions taken by FDA Field staff against applicants who put changes into effect that are required to have approved supplements [21 CFR 314.70(b)].

(3) Expiration-date extension or packaging change when the drug product is the subject of a government contract award. (This is usually requested by the Government Wide Quality Assurance Program or by Department of

Defense or Department of Veteran's Affairs procurement personnel.)

2. Procedures

a. Initial request.

(1) All requests for expedited review should reference the ANDA/AADA number and should not be directed to an individual. Upon receipt, requests for expedited review will be coded in the Management Information System (MIS).

(2) The request will be sent to the appropriate review branch where the Consumer Safety Officer (CSO) and the review chemist will make an initial recommendation.

(3) The initial recommendation will be reviewed by the Branch Chief, who will concur or not concur with the recommendation and forward it to the Division Director.

(4) The Division Director will decide whether to grant or deny the request based on the recommendations of the CSO, review chemist and Branch Chief.

(5) If the request is granted, the expedited review will be conducted as a high priority review.

(6) The branch CSO will document the decision and file it. The CSO will notify the document room staff and the appropriate decision will be entered into the MIS system.

(7) If the request for expedited review is denied, the Branch Chief or the CSO will advise the company by telephone of the decision and the reasons for the denial and then prepare a memorandum of the telephone conversation which will be placed in the ANDA/AADA file.

b. Appeal of decision.

(1) The firm may appeal the decision. Supporting documentation (referencing the ANDA/AADA number) should accompany the request for reconsideration, and be sent to the Office.

(2) The Branch Chief will make an initial recommendation

and consult with the Division director who will concur or not concur. The Division Director's decision will be final.

EFFECTIVE DATE

- This guide will be effective for all supplements filed after January 31, 1992.

NOTE

[1]Labeling supplements are not addressed in this Guide. These supplements are usually submitted in response to a request from the Office to revise what an applicant is using, usually after a change in the innovator labeling. The Office's policy on labeling supplements is stated in Policy and Procedure Guide #8-89.