PHARMACEUTICAL SCIENCES

CONSISTENT CONTAINER INFORMATION IN AN ABBREVIATED APPLICATION

CONTENTS

PURPOSE

- To ensure that generic drug firms provide consistent descriptions of container information in the stability and container/closure sections of an Abbreviated New Drug Application (ANDA) and Abbreviated Antibiotic Application (AADA). The information in these sections also should be adequate to permit a clear description of the marketed packages in the "How Supplied" section of the insert labeling.

BACKGROUND

- ANDA's and AADA's describe container/closure systems in three sections as follows: 1) the stability section where information on the specific container/closure systems used in stability testing must be provided; 2) the section on the container/closure system, in which information regarding the manufacture and quality of the container/closure components is described; and 3) in the "How Supplied" section of the Package Insert for prescription drugs, which contains a brief description of the package size.[1] If the container/closure information in these sections is unclear, not specific, or inconsistent, a reviewer may conclude that the information is incorrect, incomplete, or otherwise deficient. For example, the container section for a tablet bottle states that "Marlex 5502 HDPE" will be used to manufacture the bottle and that the metal cap is "tin-plated steel" with a wax paper liner manufactured by a specific company. The stability section only describes the container as made from "HDPE resin with a metal screw cap."

POLICY AND PROCEDURE

- The information submitted in the stability section of an application should describe the container/closure system used in stability studies in terms that easily relate to the descriptions in the container section of the application and in the

"How Supplied" section of the Package Insert. In addition to information on the batch number and strength of the drug product used, the source of the active drug substance, and the tests performed in the stability studies, the stability data should provide the following information for each container, closure or stopper:

1. construction material (i.e., composition), and the material's manufacturer and supplier;

2. complete listing of all fill volumes and container sizes and how many units are contained in each;

3. closure code number or stopper dimensions, and liner description (if any), and an indication if the closure is described as "child-resistant."

4. any filler material used as part of the container-closure system tested; and

5. description of application of torque for oral dosage forms or method of crimp sealing and container integrity testing for parenteral products.

EFFECTIVE DATE

This guide is effective upon date of publication.

NOTE

[1]21 CFR 314.50(d)(1)(ii) requires an application to contain stability data with the proposed expiration date. 21 CFR 314.55 extends this requirement to an ANDA. See also, Sec. 314.94(a)(9), Abbreviated New Drug Application Regulations; Proposed Rule dated July 10, 1989 (54 FR at 28923) and "Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics," February 1987, pp. 5, 9, and 10.