PHARMACEUTICAL SCIENCES

REAFFIRMATION OF EXPIRATION DATING PERIOD FOR ABBREVIATED APPLICATIONS

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PURPOSE

- To reaffirm the expiration dating period of 24 months for abbreviated new drug applications (ANDA's) and abbreviated antibiotic applications (AADA's) with satisfactory accelerated stability data.

BACKGROUND

- In a 1987 guidelines on stability[1], the agency indicated it would approve a tentative expiration dating period of up to 24 months if accelerated stability data submitted with an ANDA/AADA established satisfactory stability under recommended conditions (40ºC, 75% relative humidity, in most cases).

- Despite this Guideline, on occasion, for injectables and products with unit dose packaging, the Office of Generic Drugs indicated it would approve only an 18-month expiration date, rather than 24 months, even with satisfactory stability data. The reason given was that injectables, because of their liquid nature, may be more susceptible to degradation, and unit-dose packaging has more potential for failure than classical container systems. This practice was inconsistent with the Guideline and OGD now seeks to reaffirm its commitment to the Guideline.

POLICY AND PROCEDURE

- Effective immediately, a firm submitting a new application for any generic drug product may request a tentative expiration dating period of up to 24 months based on appropriate accelerated stability data in the application.

- An applicant may amend a pending unapproved application containing a request for an 18-month expiration date to request a 24-month period based on appropriate accelerated data.

- An applicant may extend the expiration dating period from 18 to 24 months for

an application approved with the shorter expiration dating period if long-term stability data from three separate production batches are available. Such changes, if reported in the next annual report, will be accepted. [See 21 CFR 314.70(d)(5).]

EFFECTIVE DATE

This guide is effective upon date of publication.

NOTE

[1]See "Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics," February 1987, pp. 43 to 45. 21 CFR 314.50(d)(1)(ii) that requires an application to contain stability data with proposed expiration dating. 21 CFR 314.55 extends this requirement to an ANDA. See Sec. 314.94(a)(9), Abbreviated New Drug Application Regulations; Proposed Rule dated July 10, 1989 (54 FR at 28921).