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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1738]

Draft Guidance for Industry on Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action." This draft guidance document provides recommendations to applicants intending to provide studies to document bioavailability (BA) or bioequivalence (BE) in support of new drug applications (NDA's), or abbreviated new drug applications (ANDA's) for locally acting nasal aerosols (metered-dose inhalers) and nasal sprays (metered-dose spray pumps).

DATES: Written comments on the draft guidance document may be submitted by *(insert date 90 days after date of publication in the Federal Register)*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>". Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one-self addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Wallace P. Adams, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5651.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled “Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.” This draft guidance provides recommendations to applicants intending to provide studies to document BA or BE in support of NDA’s or ANDA’s for locally acting nasal aerosols and nasal sprays. This guidance covers prescription corticosteroids, antihistamines, anticholinergic drug products, and the over-the-counter (OTC) mast-cell stabilizer cromolyn sodium. This guidance does not cover studies of nasal sprays included in applicable OTC monographs or studies of: (1) Metered-dose products intended to deliver drug systemically via the nasal route, or (2) drugs in nasal nonmetered dose atomizer (squeeze) bottles that require premarket approval.

This draft level 1 guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency’s current thinking on BA and BE product quality information related to nasal inhalation aerosols and nasal metered-dose spray pumps. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches to documentation of BA and BE may be used if such approaches satisfy the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments with evidence to support or refute approaches on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified

with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/16/99
June 16, 1999



Margaret M. Dotzel
Acting Associate Commissioner for
Policy Coordination

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