alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–16139 Filed 6–23–99; 8:45 am]

BILLING CODE 4160–01–F

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Draft Guidance for Industry on Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.'' This draft guidance document provides recommendations to applicants intending to provide studies to document bioavailability (BA) or bioequivalence (BE) in support of new drug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DATES: Written comments on the draft guidance document may be submitted by September 22, 1999. 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ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 September 22, 1999, 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: June 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–16140 Filed 6–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft OIG Compliance Program Guidance for Certain Medicare+Choice Organizations

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on draft compliance program guidance developed by the Office of Inspector General for Medicare+Choice Organizations that offer Coordinated Care Plans (M+CO/CCPs). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of M+CO/CCP compliance programs, and the specific elements that each M+CO/CCP should consider when developing and implementing an effective compliance program.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on July 26, 1999.

ADDRESSES: Please mail or deliver written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–4N–CPG, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–4N–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 2 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C. 20201 on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Susan Lemanski or Barbara Frederickson, (202) 619–2078, Office of Counsel to the Inspector General.

SUPPLEMENTARY INFORMATION: