4. Evaluation (20 Points)

The extent to which the applicant has developed mechanisms for evaluating and reevaluating progress toward stated goals and objectives which include feedback from its membership. The extent to which the applicant builds in the capacity for mid-course correction(s) based on those evaluations.

5. Budget (Not Scored)

The extent to which the budget is reasonable in the amount(s) requested, justified by the application content, and consistent with the intentions of this announcement.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Annual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application package.

AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241 and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

To download this and other CDC Program Announcements, you can go the CDC home page *www.cdc.gov* and click on ''funding''.

If you do not have Internet access to receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement Number of interest. Please refer to Program Announcement 99156 when you request information. Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99156, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, Telephone (770) 488–2717, Email address jcw6@cdc.gov.

For program technical assistance, contact:

Kenneth A. Schachter, M.D., M.B.A., Medical Director, Epidemiology Program Office, Office of HealthCare Partnerships, Centers for Disease Control and Prevention (CDC), Telephone 404/639–4449, Email address kbs3@cdc.gov
and
Priscilla B. Holman, M.S. Ed., Health Communication Corporate Liaison, Office of Program Planning and Evaluation, Centers for Disease Control and Prevention (CDC), Telephone: 404/639–1929, E-mail: pbh2@cdc.gov

Dated: June 18, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–16065 Filed 6–23–99; 8:45 am]

BILLING CODE 1463–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1718]

Draft Guidance for Industry on Monoclonal Antibodies Used as Reagents in Drug Manufacturing; 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 ''Monoclonal Antibodies Used as Reagents in Drug Manufacturing.'' This draft guidance provides recommendations to sponsors and applicants on the information that should be included in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), and supplements to these applications when monoclonal antibodies are used as reagents in the manufacture of drug substances and drug products that are regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

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'' or ''http://www.fda.gov/cber/guidelines.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, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. 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:

Eugenia M. Nashed, Office of New Drug Chemistry (HFD–570), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050, or

Kurt A. Brorson, Office of Therapeutics Research and Review (HFM–561), Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892–0029, 301–827–0661.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Monoclonal Antibodies Used as Reagents in Drug Manufacturing.'' This draft guidance focuses on chemistry, manufacturing, and control issues relating to the use of monoclonal antibodies as reagents in drug substance and drug product manufacture that should be addressed in IND's, NDA's, ANDA's, BLA's, and supplements to these applications.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on monoclonal antibodies used as reagents. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An

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: