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Dated: March 6, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-5865 Filed 3-7-00; 11:42 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique (QSIT); Public Workshops; Addendum

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an additional workshop in the series of FDA/Industry Exchange Workshops that were conducted in 1999. The original list of workshops was published in the **Federal Register** of September 10, 1999. Topics for discussion include: Development of Quality Systems Inspection Technique (QSIT), Compliance Program and Warning

Letter (Pilot), Management Controls, Corrective and Preventive Action, Design Controls, and Industry Perspective QSIT. This additional workshop will enhance the medical device community's understanding of QSIT, and the device industry's establishment of effective quality systems, thereby preventing regulatory problems during inspections.

Date and Time: The meeting will be held on Wednesday, March 29, 2000, 8:30 a.m. to 4:30 p.m.

Location: The meeting will be held at Carlsbad: Four Seasons Resort—Aviara, 7100 Four Seasons Point, Carlsbad, CA 92009, 760-603-6800.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with \$140 to the registrar by Monday, March 20, 2000. Fees cover refreshments, organization and site cost, and materials. Space is limited, therefore interested parties are encouraged to register early. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please inform the registrar at least 7 days in advance of the workshop. A sample registration form is provided at <http://www.fda.gov/cdrh/meetings/qsitmeetca.html>.

Contact: Marcia Madrigal, FDA, Pacific Region (HFR PA-150), 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217, 510-637-3980.

Registrar and cosponsor: Joyce W. Williams, San Diego Regulatory Affairs Network (SDRAN), c/o Arena Pharmaceuticals, Inc., 6166 Nancy Ridge Dr., San Diego, CA 92121, 858-453-7200, ext. 227, FAX 858-453-7210, e-mail: jwilliams@arenapharm.com.

SUPPLEMENTARY INFORMATION: In the fall of 1999, FDA field offices began using the QSIT nationwide as the tool for medical device inspections. QSIT was developed using a collaborative effort with stakeholders and tested in the three districts. The original list of workshops was published in the **Federal Register** of September 10, 1999 (64 FR 49192).

This additional workshop further implements the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) through working more closely with stakeholders and ensuring access to needed scientific and technical expertise. It also implements a Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) goal of providing outreach activities by Government agencies directed to small businesses.

Dated: March 6, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-5835 Filed 3-9-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0892]

Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products; 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 "PET Drug Applications—Content and Format for NDA's and ANDA's." The draft guidance is intended to assist manufacturers of certain positron emission tomography (PET) drugs in submitting new drug applications (NDA's) or abbreviated new drug applications (ANDA's) in accordance with a notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications" published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the draft guidance and the collection of information provisions by June 8, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> and at <http://www.fda.gov/cder/regulatory/pet>. Submit written requests for single copies of the draft guidance 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 to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Robert K. Leedham, Jr., Center for Drug Evaluation and Research (HFD-160), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "PET Drug Applications—Content and Format for NDA's and ANDA's." The draft guidance is intended to assist the manufacturers of certain PET drugs—fludeoxyglucose (FDG) F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection—in submitting NDA's and ANDA's in accordance with a notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications" published elsewhere in this issue of the **Federal Register**. The notice invites the manufacturers of these PET drugs to submit NDA's of the type described in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(2)) or ANDA's under section 505(j) of the act. The draft guidance states when submission of a 505(b)(2) application or ANDA is appropriate, and it describes the information that manufacturers of these PET drugs should include in each type of application.

This Level 1 draft 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 the submission of 505(b)(2) applications and ANDA's in accordance with a notice published elsewhere in this issue of the **Federal Register**. 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 requirements of the applicable statutes, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments 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 and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry: PET Drug Applications—Content and Format for NDA's and ANDA's.

Description: The draft guidance is intended to assist manufacturers of certain PET drugs in submitting NDA's or ANDA's in accordance with the notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications."

Description of Respondents: Manufacturers submitting NDA's or ANDA's for certain PET drugs.

Burden Estimate: The draft guidance is intended to assist manufacturers in preparing NDA's or ANDA's for FDG F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection submitted in accordance with a notice entitled "Positron Emission Tomography Drug Products; Safety and Effectiveness of Certain PET Drugs for Specific Indications" published elsewhere in this issue of the **Federal Register**. Most of the collection of information resulting from this draft guidance is contained in current regulations for submitting NDA's and ANDA's to FDA under part 314 (21 CFR part 314), and has already been

reviewed and approved by OMB as follows: (1) Information collection required under part 314 is approved by OMB until November 30, 2001, under OMB control number 0910-0001; (2) information collection required on Form FDA-356h (Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use) is approved by OMB until April 30, 2000, under OMB control number 0910-0338; and (3) information collection required on Form FDA-3397 (User Fee Cover Sheet) is approved by OMB until April 30, 2001, under OMB control number 0910-0297.

There are three types of submissions requested under the draft guidance that are not specifically required under part 314 or Form FDA-356h or Form FDA-3397 and, therefore, need to be approved by OMB under the PRA:

1. Cover letter—Manufacturers should include with each NDA or ANDA a signed and dated cover letter with a clear, brief introductory statement. The draft guidance specifies the information that should be contained in the cover letter: (1) Purpose of the application; (2) type of submission; (3) name, title, signature, and address of the applicant; (4) established name and proprietary name for the proposed drug product; and (5) number of volumes submitted.

2. Letter of authorization—Manufacturers using an agent or consultant to act on their behalf should include with each NDA or ANDA a letter of authorization, signed and attached to the cover letter, that identifies the authorized agent or consultant.

3. Sample statement—Manufacturers should include a sample statement when responding to an FDA request for a representative sample of the drug product proposed for marketing, the drug substance or components used in the manufacture of the drug product, or the reference standards. The draft guidance provides an example of a sample statement notifying FDA that the applicant is supplying a representative sample of the drug product, the drug substance or components, or the reference standards.

Based on FDA's experience with reviewing NDA's and ANDA's and on its knowledge of the PET drug manufacturing community, FDA has estimated, in table 1 of this document: (1) The number of respondents expected to submit cover letters, letters of authorization, and sample statements with their NDA's or ANDA's as set forth in the draft guidance; (2) the number of cover letters, letters of authorization, and sample statements that respondents will submit with their NDA's or ANDA's as set forth in the draft guidance; and (3)

the amount of time it will take respondents to submit cover letters, letters of authorization, and sample

statements with their NDA's or ANDA's as set forth in the draft guidance.

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN¹

NDA's and ANDA's	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Cover letters	50	1	50	1/2	25
Letters of authorization	20	1	20	1/2	10
Sample statements	1	1	1	1/2	.5
Total					35.5

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 6, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-5866 Filed 3-7-00; 11:42 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1130-N]

Medicare Program; March 27, 2000, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for March 27, 2000, from 8 a.m. until 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in the Multipurpose Room 800, Penthouse, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, M.D., J.D., Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-7874. News media representatives should contact the HCFA Press Office, (202) 690-6145. Please refer to the HCFA Advisory Committees Information Line (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet (<http://www.hcfa.gov/fac>) for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health

and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term. The Council held its first meeting on May 11, 1992.

The current members are: Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Mary T. Herald, M.D.(pending re-appointment); Sandral Hullett, M.D.; Stephen A. Imbeau, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Derrick K. Latos, M.D.; Dale Lervick, O.D.; Sandra B. Reed, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; Victor Vela, M.D.; and Kenneth M. Viste, Jr., M.D. The

Council Chairperson is Marie G. Kuffner, M.D.; a new chair is to be appointed.

New Council members and a new Chairperson will be sworn in during the meeting (schedule to be determined). A brief introduction and training program to familiarize the new members with their responsibilities and expectations as Council members will be conducted starting at 8 a.m. and ending at 10 a.m.

Following this orientation session, the agenda will provide for discussion and comment on the following topics:

- Collection of outpatient encounter data for risk adjustment in Medicare+Choice;

- Implementation issues for physicians; and

- Educating physicians on data collection requirements;

- Changing roles of Carrier Advisory Committees;

- Issues concerning education of physicians;

- The design of Advance Beneficiary Notices; and

- Practicing physicians' issues concerning the Medicare Provider Enrollment Form.

For additional information and clarification on the topics listed, call the contact person listed above.

Individual physicians or medical organizations that represent physicians that wish to make 5-minute oral presentations on agenda issues should contact the Executive Director by 12 noon, March 13, 2000, to be scheduled. Testimony is limited to listed agenda issues only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks should be submitted to the Executive Director no later than 12 noon, March 20, 2000, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit written comments to the Executive Director and Council members. The meeting is open