DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1938]

Review of Guidances for Industry on the Development of Generic Drug Products; Development and Use of FDA Guidance Documents; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) is providing notice to drug manufacturers on its plans for reviewing policy and procedure guides (PPG's) and other existing OGD documents that provide guidance on the development of generic drug products. This effort is being undertaken consistent with the agency's good guidance practices (GGP's) policy. The goal of this long-term effort is to identify documents that need to be revised, reformatted to fit the GGP policy, or withdrawn because they are no longer current. OGD hopes this process will result in guidances for industry that better reflect the current thinking of the agency on generic drug development. OGD also is seeking input from the public on topics for future guidance development.

DATES: Written comments by September 7, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of agency guidance documents can be obtained on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rita R. Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5845.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice explaining its policy for guidance document development, issuance, and use. The notice included an agency document entitled ''Good Guidance Practices'' (GGP's), which sets forth agency policies and procedures for developing, issuing, and using guidance documents.

Since the early 1990's, OGD has developed and issued more than 40 PPG's to provide information to industry on the development of generic drug products and to set forth procedures for the review of generic drug applications. In addition, other guidance has been provided in the form of letters and other communications to industry. OGD is undertaking a long-term effort to review all of its guidances and identify those that need to be revised, those that need to be reformatted for consistency with GGP's, and those that need to be withdrawn because they are no longer current. As an initial step in this process, OGD is planning to withdraw a number of drug-specific bioequivalence guidances that are outdated and no longer reflect the current thinking of the agency. Guidances that are being withdrawn include the following:

Guidance	Date of Issuance
Alprazolam (tablets)	November 27, 1992
Bumetanide (tablets)	April 23, 1993
Captopril (tablets)	May 13, 1993
Carbidopa and Levodopa (tablets)	June 19, 1992
Cefaclor (capsules and suspension)	April 23, 1993
Diflunisal (tablets)	May 16, 1992
Diltiazem Hydrochloride (tablets)	May 16, 1992
Flurbiprofen (tablets)	June 8, 1995 (2d Revision)
Gemfibrozil (tablets and capsules)	June 15, 1992 (Revision)
Guanabenz Acetate (tablets)	April 23, 1993
Hydroxychloroquine Sulfate (tablets)	December 28, 1995
Indapamide (tablets)	April 23, 1993
Ketoprofen (capsules)	April 23, 1993
Leucovorin Calcium (tablets)	August 4, 1988 (Revision)
Medroxyprogesterone Acetate (tablets)	September 17, 1987 (Revision)
Metoprolol Tartrate (tablets)	June 12, 1992
Nadolol (tablets)	May 16, 1992
Naproxen (tablets)	June 8, 1995 (Revision)
Nortriptyline Hydrochloride (capsules)	June 12, 1992
Pentoxifylline (extended-release tablets)	December 22, 1995
Pindolol (tablets)	April 23, 1993
Piroxicam (capsules)	June 15, 1992
Ranitidine Hydrochloride (tablets)	April 23, 1993
Trazodone Hydrochloride (tablets)	April 30, 1988 (Revision)

It is possible that some of the remaining drug-specific guidances on bioavailability and bioequivalence also will be withdrawn after they are reassessed. However, several CDER guidances currently under development will serve as core guidances on bioavailability and bioequivalence once they have been finalized, and they will replace the product-specific guidances. On rare occasions, the agency may wish to provide bioavailability and bioequivalence guidance for specific drug products, and these will be developed and issued consistent with the agency's GGP policy.

The agency welcomes public comment on its efforts to review existing guidances related to the development of generic drugs and revise, reformat, or withdraw them as appropriate. The agency also is requesting public comment on topics for future guidance development regarding generic drugs.

This information is being issued consistent with FDA's GGP's. It does not

create or confer any rights for or on any person and does not operate to bind FDA or the public.

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

Dated: June 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–17331 Filed 7–7–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0209 and HCFA–R–0245]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies (HCFA–3006–IFC) and Supporting Regulations in 42 CFR 484.11 and 484.20; *Form No.:* HCFA–R–0209 (OMB# 0938–0761); *Use:* The information collection requirements contained in the HCFA–3006 regulation state that HHAs must report data from the OASIS data set as a condition of participation for HHAs. Specifically, the above named rule provides guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to HCFA. These requirements are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs.; *Frequency:* As determined by HHA and monthly; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government; *Number of Respondents:* 10,492; *Total Annual Responses:* 10,492; *Total Annual Hours:* 1,274,866.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Use of Outcome and Assessment Information Set (OASIS) as Part of the Conditions of Participation for Home Health Agencies (HCFA–3007–F) and Supporting Regulations in 42 CFR 484.55; *Form No.:* HCFA–R–0245 (OMB# 0938–0760); *Use:* These information collection requirements revise the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program. Specifically, this final rule requires that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, this final rule requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care.; *Frequency:* Upon patient assessment; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, Local, or Tribal Government; *Number of Respondents:* 10,492; *Total Annual Responses:* 10,492; *Total Annual Hours:* 1,238,056.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 30, 1999.

John Parmigiani,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–17374 Filed 7–7–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis of Proarrhythmic Medicines and Primary Cardiac Arrest.

Date: August 9, 1999.

Time: 7:00 PM to 9:00 PM.

Agenda: To review and evaluate grant applications.