DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0514]

Draft Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' This draft guidance provides recommendations for including information in abbreviated new drug applications (ANDA's) and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances.

DATES: Written comments on the draft guidance may be submitted by September 22, 1998. 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ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Robert W. Trimmer, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' This draft guidance provides information on the following: (1) Qualifying impurities found in the drug substance used for ANDA via a comparison with impurities found in the related United States Pharmacopeia (USP) monograph, scientific literature, or innovator material; (2) qualifying impurities found at higher levels in the drug substance used for ANDA than found in the related USP monograph, scientific literature, or innovator material; (3) qualifying impurities in the drug substance used for ANDA which are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels, below which qualification is not needed.

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 the content and qualification of impurities in drug substances produced by chemical syntheses that are used in generic drug products. 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, on or before September 22, 1998, 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19714 Filed 7–23–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–250,254]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Secondary Payer Information Collection and Supporting Regulations 42 CFR 489.20; *Form No.:* HCFA–250,254 OMB #0938–0214; *Use:* This questionnaire will collect information from beneficiaries on health insurance coverage that is primary to Medicare. This information is necessary in order for HCFA to identify those Medicare beneficiaries who have group health insurance that would pay before Medicare, resulting in savings to the Medicare Trust Fund. Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. HCFA contracts with health insuring organizations, herein referred to as intermediaries and carriers, to process Medicare claims. HCFA charges its Medicare intermediaries and carriers with various tasks to detect MSP cases; develops and disseminates tools to enable them to better perform their tasks; and monitors their performance in achievement of their assigned MSP functions. Because intermediaries and carriers are also marketing health insurance products that may have liability when Medicare is secondary, the MSP provisions create the potential for conflict of interest. Recognizing this inherent conflict, HCFA has taken steps to ensure that its intermediaries and carriers process claims in accordance with the MSP provisions, regardless of what other insurer is primary. *Frequency:* One time only; *Affected Public:* Individuals or Households; *Number of Respondents:* 14,204,000; *Total Annual Responses:* 14,204,000; *Total Annual Hours:* 773,240.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, 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: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 15, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Security and Standards Group, Health Care Financing Administration.

[FR Doc. 98–19730 Filed 7–23–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–18F5]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Application for Hospital Insurance and Supporting Regulation 42CFR 406.7; *Form No.:* HCFA–18F5, OMB # 0938–0251; *Use:* The HCFA 18F5 is used to establish entitlement to hospital insurance and supplementary medical insurance for beneficiaries entitled under title XVII of the Social Security Act only. *Frequency:* One time submission; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, Farms, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 12,500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 14, 1998.

John P. Burke III,

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

[FR Doc. 98–19731 Filed 7–23–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center of Research Resources; 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)(b), 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 Center for Research Resources Special Emphasis Panel General Clinical Research Centers Review Committee.

Date: September 9, 1998.

Time: 8:00 am to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: University of Pittsburgh, Magee-Women's Hospital, 300 Halket Street, Pittsburgh, PA 15213.

Contact Person: John L. Meyer, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, 301–435–0822.

Name of Committee: National Center for Research Resources Special Emphasis Panel Biomedical Research Technology.

Date: October 4–6, 1998.

Time: October 4, 1998, 6:00 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: John L. Meyer, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, 301–435–0822.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: July 17, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–19796 Filed 7–23–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of 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 meetings of the National Advisory Research Resources Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.