DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Review and Revision of Guidelines for Industry on the Development of Generic Drug Products; Development and Use of Food and Drug Administration Guidance Documents; Update and Withdrawal of Guidelines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; update and withdrawal of guidances.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) is updating drug manufacturers on OGD efforts to review policy and procedure guides (PPGs) and other existing OGD documents that provide guidance on the development of generic drug products. We are also announcing the withdrawal of a list of PPGs that have become obsolete or have been replaced with other guidances or agency directives (manuals for policy and procedure guides (PPGs) and other existing OGD documents) that have become outdated and no longer reflect the current thinking of the agency.

This notice has a twofold purpose: (1) It updates manufacturers on the status of OGD efforts to review existing guidances, and (2) it announces the withdrawal of 30 PPGs that are obsolete. The PPGs that are being withdrawn are listed below. In each case, the reason for the withdrawal has been provided in parentheses.

• 1–89 “Correspondence Practices” (The guidance “Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications” describes current correspondence practices.)
• 3–89 “Handling Telephone Inquiries on Status of Processing from Applicants or Their Representatives” (MAPP 5020.1 has been issued on this topic.)
• 4–89 “Microbiology Consults” (It is no longer needed as OGD has its own microbiology staff.)
• 6–89 “Not Approvable Actions for ANDA and AADA Supplements” (The guidance “Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications” describes current correspondence practices.)
• 8–89 “Changes in the Labeling of ANDAs Subsequent to Revision of Innovator Labeling” (This guidance has been superseded by PPG 60.6.)
• 9–89 “Delivery of Documents to the Office of Generic Drug’s Document Room; Providing Requested Documents to Messengers and Other Representatives of ANDA/AADA Applicants” (This describes interactions with messengers and other representatives that have been overtaken by advances in technology.)
• 10–89 “Meetings With Pharmaceutical Firm Employees or Their Representatives” (This is addressed in CDER MAPP 4512.1.)
• 11–89 “Shredding of Carbons and Draft Reviews and Letters” (This has been overtaken by advances in technology.)
• 12–89 “Number of Manufacturing Sites Permitted in an ANDA or AADA” (This has been superseded by the guidance “Variations in Drug Products that May Be Included in a Single ANDA.”)

• 13–89 “Testing Requirements Applicable to Finished Dosage Forms Manufactured Outside the United States” (This material will be incorporated into the center’s guidance on “Stability Testing of Drug Substances and Drug Products,” which issued a draft in June 1998.)
• 14–89 “Signatory Concurrence and Agreement on Final Typed Reviews and Letters and Other Items in the Administrative File” (This is addressed by MAPP 4151.1.)
• 16–90 First In-First Reviewed Policies (This was superseded by PPG 39–93, then addressed by MaPP 5240.3.)
• 18–90 “Requests for Expedited Review of Supplements to Approved ANDAs and AADAs” (This became MaPP 5240.1.)
• 19–90 “Availability of Labeling Guidance” (This became MaPP 5230.1.)
• 20–90 “Variations in Solid Oral Dosage Forms and Injectables That Can Be Included Within a Single ANDA” (This guidance has been superseded by the guidance “Labeling Agreements for Drug Products That May Be Included in a Single ANDA.”)

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• 33–92 “Consistent Container Information in an Abbreviated Application” (This is addressed by MaPP 5225.2.)
• 34–92 “Implementation of the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Final Policy” (Revised October 3, 1992 (An agency-level policy addresses this topic.)
• 35–92 “Revision of Exhibit Batch Requirements for Abbreviated Antibiotic Drug Applications” (This became MaPP 5223.1; the MaPP was then withdrawn with repeal of section 507 of the act.)
• 36–92 “Submission of an Investigational New Drug Application to the Office of Generic Drugs” (This is addressed by MaPP 5240.4.)
• 37–92 “Management of Office and Center Committees” (This was previously withdrawn per memo dated February 14, 1997, because of center committee reorganization.)
• 38–93 “Restatement of the Office of Generic Drugs First In-First Reviewed Policy and Modifications of the Exceptions to the Policy Regarding Minor Amendments” (This is addressed by MaPP 5240.3.)
• 40–94 “Scoring Configuration of Generic Drug Products” (This is addressed by MaPP 5223.2.)
• 41–95 “Packaging of Test Batches” (This is addressed by MaPP 5225.1.)

A number of other PPGs and other OGD documents are undergoing revision. Some of them will be issued as MaPPs; others will be revised and reissued in the form of guidances for industry consistent with the GGP regulation.

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

This information is being issued consistent with FDA’s GGP. 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 to the Division of Dockets Management (see ADDRESSES) written comments. Two copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.


Jeffrey Shuren,
Assistant Commissioner for Policy.
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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

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 meeting.

The meeting 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: Cardiovascular Sciences Integrated Review Group, Pathology A Study Section.


Time: 7:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Terrace Hotel, 1515 Rhode Island Ave., NW., Washington, DC 20005.

Contact Person: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Genomics Shared Instruments.

Date: October 21, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2205, MSC 7802, Bethesda, MD 20892, (301) 435–4511.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Pathophysiological Sciences Integrated Review Group, Alcohol and Toxicology Subcommittee 1.


Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.