GENERAL SERVICES ADMINISTRATION

Performance Review Boards for Small Client Agencies Services by the General Services Administration, Names of Members

Sec. 4314©(1) through (5) of Title 5 U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Performance Review Boards. The board shall review and evaluate the initial appraisal by the supervisor of a senior executive's performance, along with any recommendations to the appointing authority relative to the performance of the senior executive. The Performance Review Board also shall make recommendations as to whether the career executive should be recertified, conditionally recertified, or not recertified.

As provided under Section 601 of the Economy Act of 1932, amended 31 U.S.C. 1525, the General Services Administration through its Agency Liaison Division, provides various personnel management services to a number of diverse Presidential commissions, committees, boards and other agencies through reimbursable administrative support agreements. This notice is processed on behalf of the client agencies, and it supersedes all other notices in the **Federal Register** on this subject. Because of their small size, a Performance Review Board register has been established in which SES members from the client agencies participate. The Board is composed of SES members from various agencies. From this register of names, the head of each client agency will appoint executives to a specific board to serve a particular client agency.

The members whose names appear on the Performance Review Board standing roster to serve client agencies are:

Barry M. Goldwater Scholarship and Excellence In Education Foundation

Gerald J. Smith, Executive Secretary

Committee for Purchase From People Who Are Blind or Severely Disabled

Beverly L. Milkman, Executive Director

Federal Retirement Thrift Investment Board

David L. Black, Director of Accounting
Stratos D. Valakis, Director of Contracts and Administration
Lawrence E. Stiffler, Director of Automated Systems
Alisone M. Clark, Director of Benefits and Program Analysis
Veda R. Charrow, Director of Communications
Thomas J. Trabucco, Director of External Affairs
Peter B. Mackey, Director of Investments
John J. Omeara. General Counsel
James B. Petrick, Deputy General Counsel
Elizabeth S. Woodruff, Associate General Counsel

Defense Nuclear Facilities Safety Board

Kenneth M. Pusateria, General Manager
Joseph R. Neubeiser, Deputy General Manager
Richard A. Azaro, Deputy General Counsel for Policy and Litigation
George W. Cunningham, Technical Director
Wallace R. Kornack, Technical Advisor for Technical Studies

Harry S. Truman Scholarship Foundation

Louis H. Blair, Executive Secretary

Japan-United States Friendship Commission

Eric J. Gangloff, Executive Director

Office of Navajo and Hopi Indian Relocation

Christopher J. Bavasi, Executive Director
Michael J. McAlister, Deputy Executive Director

Arctic Research Commission

Garrett W. Brass, Executive Director

National Mediation Board

Ronald M. Etters, General Counsel
Stephen E. Crable, Chief of Staff

Dated: November 12, 1998.

Elaine Dade,

Director, Laision Division.

[FR Doc. 98–31840 Filed 11–27–98; 8:45 am]

BILLING CODE 6820–23–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1019]

BF Goodrich Specialty Chemicals; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BF Goodrich Specialty Chemicals has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid as a component of cap liners used on bottles in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4631) has been filed by BF Goodrich Specialty Chemicals, 9911 Brecksville Rd., Cleveland, OH 44141. The petition proposes to amend the food additive regulations in § 177.1210 *Closures with sealing gaskets for food containers* (21 CFR 177.1210) to provide for the safe use of polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid as a component of cap liners used on bottles in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 10, 1998.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–31692 Filed 11–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0994]

Draft Guidance for Industry on BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation; 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 ''BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation.'' This

draft guidance provides recommendations to sponsors of new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and holders of drug master files or veterinary master files who intend, during the postapproval period, to change the site of manufacture, the scale of manufacture, the equipment, the specifications, and/or the manufacturing process of intermediates in the synthetic pathway leading to the drug substance.

DATES: Written comments on the draft guidance may be submitted by March 31, 1999. General comments on the 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/cvm''. 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 that 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. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kasturi Srinivasachar, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5376, or David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2701.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance defines recommended chemistry, manufacturing and controls tests, and documentation in support of each change. The draft guidance applies to synthetic drug substances and the synthetic steps involved in the preparation of semisynthetic drug substances. It is limited to structurally well-characterized drug substances where impurities can be monitored at the levels recommended. The draft guidance covers changes as follows: (1) Site, scale, and equipment changes involving the synthetic steps up to and including the step that produces the final intermediate, (2) specification changes for raw materials, starting materials, and intermediates, excluding the final intermediate, and (3) manufacturing process changes involving the synthetic steps up to and including the final intermediate. Postapproval changes affecting: (1) Synthetic peptides, (2) oligonucleotides, (3) radiopharmaceuticals, or (4) drug substances derived exclusively by isolation from natural sources or produced by procedures involving biotechnology are not addressed in this document.

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 postapproval changes for the manufacture of intermediates in drug substance syntheses. 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: November 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31765 Filed 11–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0996]

Draft Guidance for Industry on General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological 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 ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products.'' This document is intended to assist applicants who plan to conduct pharmacokinetic (PK) studies in the pediatric population so that drugs and biological products can be labeled for pediatric use.

DATES: Written comments may be submitted on the draft guidance by January 29, 1999. 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'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or 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. Copies of this guidance may also be obtained by fax from 1–888–CBERFAX or 301–827–3844 or by mail from the CBER Voice Information System at 800–835–4709 or 301–827–1800.

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: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products.'' The guidance is intended to assist applicants who plan to conduct pharmacokinetic (PK) studies in the pediatric population so that drugs and biological products can be labeled for pediatric use.

In the past few years, the agency has addressed the need for greater information on the use of drugs in the pediatric population. In the **Federal**