organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests for the committee within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2), relating to advisory committees.

Dated: July 24, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–20080 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members on Public Advisory Committees; Science Board to the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Science Board to the Food and Drug Administration (the board) administered from FDA's Office of Science. Nominations will be accepted for upcoming vacancies that may or will occur on the board during the next 24 months.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees, and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically disabled candidates. Final selections from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: All nominations must be received by September 2, 1997.

ADDRESSES: All nominations for membership and curricula vitae from academia, industry, and government, except for general public representatives (consumer-nominated members), should be sent to Susan K. Meadows (address below). All nominations for general public representatives (consumer-nominated members) should be sent to Annette J. Funn (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership, except for general public representatives: Susan K. Meadows, Office of Science (HF–32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4591.

Regarding all nominations for general public representatives: Annette J. Funn, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5006.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members to serve on the board for upcoming vacancies that may or will occur on the board during the next 24 months.

Function

The function of the board is to provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in academia and industry. Additionally, the board provides advice to the agency on keeping pace with technical and scientific evolutions in the field of regulatory science, on formulating an appropriate research agenda and on upgrading its scientific and research facilities to keep pace with these changes. The board also provides the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Criteria for Members

Persons nominated for membership shall have exceptional accomplishments and expertise in science, or executive level experience in scientific programmatic or laboratory management involving scientific endeavors appropriate to the work of the board and the interests of FDA. Disciplines or expertise of particular interest include biomedical technology with application to medical devices, biologics and vaccine development and research, and genetics. The term of office is 4 years.

General Public Representatives (Consumer-nominated Members)

FDA currently attempts to place members on advisory committees who are nominated by consumer organizations. These members are recommended by a consortium of 12 consumer organizations that has the responsibility for screening, interviewing, and recommending consumer-nominated candidates with appropriate scientific credentials. Candidates are sought who are aware of the consumer impact of committee issues, but who also possess enough technical background to understand and contribute to the committee's work. The agency notes, however, that for some advisory committees, it may require such nominees to meet the same technical qualifications and specialized training required of other expert members of the committee. The term of office for these members is up to 4 years, depending on the appointment date. Nominations are invited for consideration for membership as openings become available.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the board. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the board, and appears to have no conflict of interest that would preclude board membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 24, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–20082 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F-0305]

Goldschmidt Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Goldschmidt Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of siloxanes and silicones; cetylmethyl, dimethyl, methyl 11-methoxy-11-oxoundecyl as a pigment dispersant in all pigmented polymers intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by September 2, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

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 7B4550) has been filed by Goldschmidt Chemical Corp., c/o Keller and Heckman, 1001 G St., NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3725 *Pigment dispersants* (21 CFR 178.3725) to provide for the expanded safe use of siloxanes and silicones; cetylmethyl, dimethyl, methyl 11-methoxy-11-oxoundecyl as a pigment dispersant in all pigmented polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before September 2, 1997, submit to the Dockets Management Branch (address above) written comments. 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 11, 1997.

Laura M. Tarantino,

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

[FR Doc. 97–20079 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0299]

International Conference on Harmonisation; Draft Guideline on Ethnic Factors in the Acceptability of Foreign Clinical Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline entitled ''Ethnic Factors in the Acceptability of Foreign Clinical Data.'' The draft guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline provides guidance on regulatory and development strategies to permit clinical data collected in one region to be used for the support of drug and biologic registrations in another region while allowing for the influence of ethnic factors.

DATES: Written comments by October 29, 1997.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guideline may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Barbara G. Matthews, Center for Biologics Evaluation and Research (HFM–570), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5094.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In March 1997, the ICH Steering Committee agreed that a draft guideline entitled ''Ethnic Factors in the Acceptability of Foreign Clinical Data'' should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this