

proposed trade name GILENIA (fingolimod hydrochloride) 0.5 milligram (mg) capsules, by Novartis Pharmaceuticals Corp. The proposed indication for this new drug product is treatment of relapsing forms of multiple sclerosis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 26, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 18, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will

notify interested persons regarding their request to speak by May 19, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 1, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-7698 Filed 4-5-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0004]

Memorandum of Understanding Between the Food and Drug Administration, United States Department of Health and Human Services and the National Alliance for Hispanic Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, U.S. Department of Health and Human Services and the National Alliance for Hispanic Health. The purpose of the MOU is to establish the terms for collaboration to enhance the diversity pool of candidates and to promote shared interests in increasing science and public health internship opportunities for socio-economically disadvantaged students.

DATES: The agreement became effective January 21, 2010.

FOR FURTHER INFORMATION CONTACT:

Mary C. Hitch, Senior Policy Advisor, Office of External Relations, Food and Drug Administration, 5600 Fishers Lane, rm. 15A07, Rockville, MD 20857, 301-827-4406.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160-01-S

MOU Number: 225-10-0006

Memorandum of Understanding
between
United States Department of Health and Human Services
Food and Drug Administration
and
National Alliance for Hispanic Health

I. Purpose

The Food and Drug Administration, U.S. Department of Health and Human Services, and the National Alliance for Hispanic Health (the Alliance) share interests in promoting scientific progress through exchange of scientific capital in diverse fields of science that affect human and animal health and medicine. Both institutions foresee benefits from scientific and public health orientation for socio-economically disadvantaged students to foster a well-grounded foundation in interdisciplinary science on which scientific learning can grow. This Memorandum of Understanding (MOU) establishes the terms for collaboration to enhance the diversity of the pool of candidates and to promote shared interests in increasing science and public health internship opportunities for socio-economically disadvantaged students.

II. Background

FDA is responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the United States food supply and cosmetics. FDA is also responsible for advancing the public health by helping to speed innovations that make medical products and foods more effective, safer, and more affordable. FDA also helps the public get accurate, scientific-based information need to use medical products and foods to improve their health.

The Alliance, a nonprofit entity as described in section 501(c)(3) of the Internal Revenue Code of 1968, is the oldest and largest network of Hispanic health and human service providers for the target population. As an umbrella organization, the Alliance represents thousands of healthcare providers across the nation who provide services to more than 15 million health consumers each year. The Alliance is a recognized leader within the United States among Hispanic and socio-economically disadvantaged communities. The Alliance works with diverse organizations such as community-based organizations, foundations, corporations, government agencies, universities, and private industry to carrying out its mission with the objective of improving public health. The Alliance also works with these organizations to support internship opportunities for socio-

economically disadvantaged students to gain exposure to careers in science and public health.

III. Substance of Agreement:

FDA enters this MOU with the Alliance to: 1) Expose socio-economically disadvantaged students to scientific and allied health professions through experiential and educational internship opportunities in science, public health and biomedical sciences in mentored laboratory settings, and 2) Promote student education and matriculation into the science, public health and biomedical science professions to contribute to a diversified pool of candidates for employment opportunities in science and public health.

IV. Resource Obligations

This MOU represents the broad outline of the parties' present intent to enter specific agreements for collaborative efforts between FDA and the Alliance. It does not create binding or enforceable obligations against any party to commit resources. This MOU does not affect or supersede any existing or future agreements or arrangements among the parties. It also does not affect the ability of the parties to enter other agreements or arrangements related to this MOU. This MOU and all associated agreements will be subject to the applicable policies, regulations and statutes affecting FDA, and the Alliance and its members.

V. Further Information:

Citizenship and security clearance: Individuals participating in the MOU will be United States citizens or permanent residents. Individuals participating as interns in the internship program must comply with all applicable federal regulations. FDA officials may obtain information from participating individuals for security clearance or access to FDA facilities and offices. Information obtained may be re-disclosed to other Federal agencies for the above purposes and in fulfillment of official responsibilities to the extent that such disclosure is permitted by law.

Conflict of Interest: Individual interns participating in activities under this MOU who are not U.S. Government employees will be expected to abide by conflict of interest rules and policies as specified by FDA. This may require participants to disclose their financial holdings and those of their spouse and minor children, and may limit their ability to accept gifts and have employment with entities that are substantially regulated by FDA. The parties to the MOU will be advised of any potential conflict so that conflicting assignments can be avoided consistent with the HHS/FDA requirements. If at any time prior to or during the performance of the activities under the MOU, the parties or the program participant believe

that a potential or actual conflict exists, the parties or participant must notify the appropriate authorities within their respective institutions and contact the designated FDA official listed on the MOU so that the necessary action/s can be undertaken. A determination will be made by FDA as to whether a conflict of interest exists and, if so, as to how to resolve or mitigate it. Parties to the MOU will make every effort to avoid activities or relationships that would cause a reasonable person to question the impartiality of their actions.

Nonpublic Information: All participants in this program must recognize that information to which they have access that contains any of the following types of information must be protected from unauthorized disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 U.S.C. § 1905), the Privacy Act (5 U.S.C. § 552a), the Freedom of Information Act (5 U.S.C. § 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

Liaison Officers:

Mary C. Hitch
Senior Policy Advisor
Office of External Relations
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15A07
Rockville, Maryland 20857
301-827-4406 (Telephone)
301-827-8030 (FAX)

Adolph Falcon
Vice President
National Alliance for Hispanic Health
1501 16th Street, N.W.
Washington, D.C. 20036
202-387-5000

V. Terms, Termination, Modification

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until five year after the date

of signature and may be modified by mutual consent or may be terminated by either party on a 60- day advance written notice to the other.

Approved and Accepted:

NATIONAL ALLIANCE FOR HISPANIC HEALTH

BY:

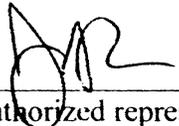

Signature of authorized representative

1/20/10
Date

JANE L. DELGADO, PH.D.
President and Chief Executive Officer
National Alliance for Hispanic Health

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY:


Signature of authorized representative

12/27/9
Date

JOSHUA M. SHARFSTEIN, M.D.
Principal Deputy Commissioner of Food and Drugs
Department of Health and Human Services

[FR Doc. 2010-7673 Filed 4-5-10; 8:45 am]

BILLING CODE 4160-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0004]

[FDA 225-10-0007]

Memorandum of Understanding Between the Food and Drug Administration, United States Department of Health and Human Services and the Association of Minority Health Profession Schools, Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the FDA, U.S. Department of Health and Human Services and the Association of Minority Health Profession Schools, Inc. The purpose of the MOU is to establish the terms for collaboration to enhance the diversity pool of candidates and to promote shared interests in increasing science and public health internship opportunities for socio-economically disadvantaged students.

DATES: The agreement became effective January 20, 2010.

FOR FURTHER INFORMATION CONTACT: Mary C. Hitch, Senior Policy Advisor,

Office of External Relations, Food and Drug Administration, 5600 Fishers Lane, rm. 15A07, Rockville, MD 20857, 301-827-4406

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160-01-S