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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier JCooke

[Docket No. 2004N–0086]

Diabetes: Targeting Safe and Effective Prevention and Treatment; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: FDA/National Institutes of Health (NIH) Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment. The purpose of the public meeting is to define the current state of the prevention and management of diabetes and to identify and discuss therapeutic gaps and hurdles to safe and effective prevention and treatment of type 1 and type 2 diabetes mellitus. The public meeting is intended to provide assistance to FDA, clinical and basic scientists, and the interested pharmaceutical industry in their efforts to reduce the burden of diabetes and improve the health of all people with diabetes.

DATES: The public meeting will be held on May 13, 2004, from 8:30 a.m. to 4:30 p.m. and on May 14, 2004, from 8 a.m. to 12 noon. Registration is required to attend the public meeting and must be received by April 30, 2004, at 3 p.m.

ADDRESSES: The public meeting will be held at the Natcher Conference Center, Bldg. 45, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD. Important information about transportation and directions to the NIH campus,

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parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm.*

Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm.* Due to the limited available parking, visitors are encouraged to use public transportation.

FOR FURTHER INFORMATION CONTACT:

For General Information: James Cross, Center for Drug Evaluation and Research, Food and Drug Administration (HFD–020), 5515 Security Lane, Rockville, MD 20852, 301–443–5355, FAX: 301–480–8329, e-mail: *james.cross@fda.hhs.gov*, or

Sanford Garfield, National Institute for Diabetes and Digestive and Kidney Diseases, National Institutes of Health, 6707 Democracy Blvd., rm. 685, Bethesda, MD 20892–5460, e-mail: *garfields@ep.niddk.nih.gov.*

For Registration Information: Iain MacKenzie, The Hill Group, 6903 Rockledge Dr., suite 540, Bethesda, MD 20817, 301–897–2789, FAX 301–897–9587, e-mail: *imackenzie@thehillgroup.com*

SUPPLEMENTARY INFORMATION:

I. Background

Diabetes mellitus constitutes a significant and growing threat to the U.S. public health, largely through its comorbid clinical features and long-term

complications, including blindness, kidney disease, amputations, and cardiovascular disease. On January 31, 2003, FDA launched an initiative to improve the development and availability of innovative medical products by creating clearer guidance on priority therapeutic areas, including diabetes. Information about the initiative is available on the Internet at *http://www.fda.gov/bbs/topics/news/2003/beyond2002/report.html.*

As outlined in the initiative, FDA intends to develop regulatory guidance on diabetes in collaboration with scientists and relevant parties through public meetings such as the FDA/NIH Joint Symposium on Diabetes: Targeting Safe and Effective Prevention and Treatment. This public meeting also relates to a recent initiative of the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDKD) entitled "Bench to Bedside, Research on Type 1 Diabetes and Its Complications," which aims to translate molecular understanding of type 1 diabetes into novel therapies.

The public meeting will provide a forum for discussion of diabetes-related topics, including the following topics:

- Important disease outcomes that are or should be targeted in the development of drugs, devices, and cell-based therapies for type 1 and/or type 2 diabetes;

- Issues surrounding the use of surrogate or intermediate measures of clinical effect in assessments of novel therapeutic approaches to prevention and treatment; and

- Clinical, scientific, and regulatory issues surrounding development of new medical technologies for the treatment of metabolic syndrome and for the prevention of type 2 diabetes.

Participants include FDA and NIH staff, academic experts from the United States and abroad, members of trade associations representing commercial industry, and representatives of the major diabetes patient advocacy groups.

FDA and NIH are currently developing a web page where interested persons can register to attend the public meeting, submit comments, and to obtain related information. Information about the public meeting will be posted at *http://www.niddk.nih.gov/fund/other/conferences.htm.*

II. Registration

If you would like to attend the public meeting, you must register with Iain MacKenzie (see **FOR FURTHER INFORMATION CONTACT**) by April 30, 2004, at 3 p.m. by providing your name, title, organizational affiliation, address, telephone, fax number (optional), and e-mail address (optional). Registration will be conducted on a first-come, first-served basis, and seating will be limited. To expedite processing, this registration information may also be faxed or e-mailed to Iain MacKenzie. If you need special accommodations due to a disability, please contact Iain MacKenzie at least 7 days in advance.

The public meeting will include morning and afternoon sessions during which a discussion of diabetes and related issues associated with diabetes prevention and treatment will be presented. FDA and NIH are asking experts to provide presentations on specific issues, with discussion time following each presentation.

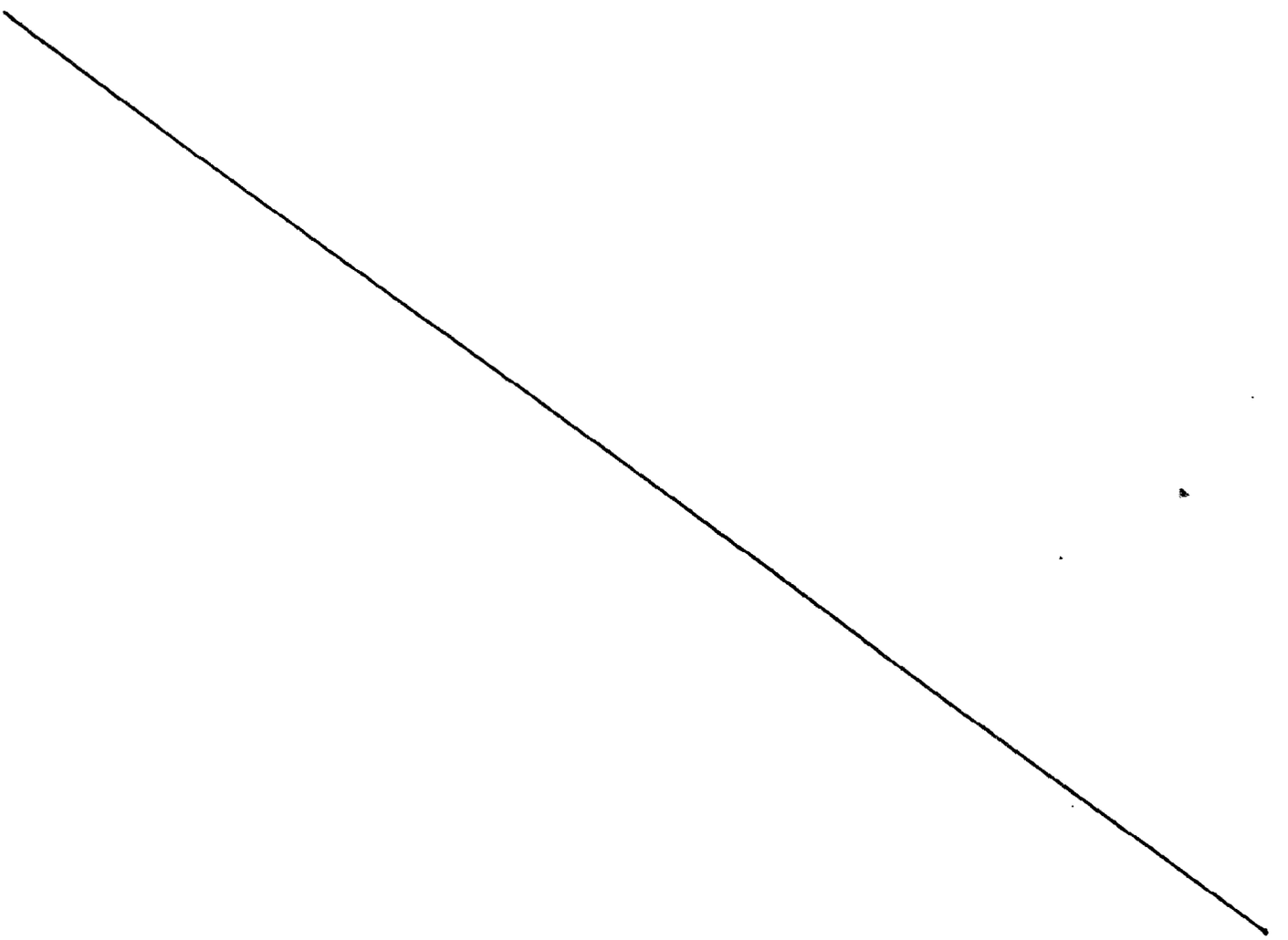
III. Comments

The administrative record of this public meeting will remain open for 30 days after the public meeting. Interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments by June 11, 2004. You may also send comments to the Division of Dockets

Management via e-mail to *FDADockets@oc.fda.gov*. Submit two paper copies of comments, identified with the docket number found in brackets in the heading of this document. Individuals may submit one paper copy. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments may be placed on the Internet and, if so, will be available for public viewing.

IV. Meeting Notes

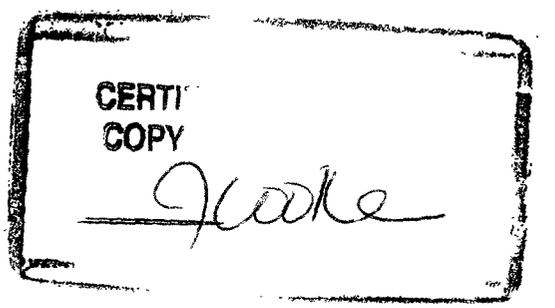
You may request a copy of the notes of the public meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15



working days after the public meeting, at a cost of 10 cents per page. You may examine the notes of the public meeting after June 11, 2004, at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: FEB 27 2004
February 27, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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