DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

National Antimicrobial Resistance Monitoring System Program
Subcommittee of the Science Advisory Board to the Food and Drug
Administration; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing the following public meeting: Science Board to the FDA National Antimicrobial Resistance Monitoring System (NARMS) Program Subcommittee meeting. The topic to be discussed is the National Antimicrobial Resistance Monitoring System (NARMS) Program. The subcommittee will provide advice to the Science Advisory Board to FDA regarding the NARMS program.

Date and Time: The public meeting will be held on April 10, 2007, beginning at 9 a.m.

Location: The DoubleTree Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact: Carlos Pena, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, e-mail: Carlos.Pena@fda.hhs.gov.

Agenda: The subcommittee will evaluate the NARMS program and address four questions relevant to the continued success of the program including:

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- (1) Are there inherent biases in the sampling strategies employed in NARMS? If so, how can they be improved to ensure that the data and interpretation are scientifically sound given current resources?
- (2) Are there epidemiological and/or microbiological research studies that would better serve the goals of NARMS and the regulatory work of FDA?
- (3) Are current plans for data harmonization and reporting appropriate? If not, what are the top priorities for advancing harmonized reporting? and
- (4) Are the current NARMS international activities adequate to address the worldwide spread of antimicrobial-resistant foodborne bacteria?

The subcommittee will discuss the NARMS Program and hear comments on the NARMS Program, including oral presentations from the public on scope, strengths, weaknesses, and areas for improvement.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone and fax number, and e-mail address), and written material and requests to make oral presentations, to the contact person on or before March 28, 2007. Interested persons may present data, information, or views, orally or in writing, on the issues pending before this subcommittee. Written submissions may be made to the contact person on or before March 28, 2007. Oral presentations from the public will be scheduled to begin at 11 a.m. on April 10, 2007. 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 March 20, 2007. 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 person regarding their request to speak by March 20, 2007.

If you need special accommodations due to a disability, please notify the hotel (301–468–1100) at least 7 days in advance of the meeting.

Transcripts: Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: 3/14/07

March 14, 200%.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

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