

establishment size. The product types are vitamins and minerals, herbals and botanicals, herbal and botanical extracts, amino acids, proteins, animal extracts, tea-like products, concentrates/metabolites/constituents, and other dietary supplements. The survey is designed to determine the extent to which firm's operations use written procedures and maintain records to ensure that: (1) Personnel have the

proper education, training and experience and are knowledgeable in disease control and other safety concerns; (2) buildings and facilities are maintained against contamination; (3) equipment is cleaned and sanitized; (4) quality control and laboratory operations determine that certificates of analysis are reliable and that identity and adulteration tests are conducted on raw materials and in-process

formulations; (5) production and process controls use master and batch records as well as other records; (6) warehousing and distribution operations maintain records for forward and backward tracing of product; and (7) consumer complaints are handled and documented.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Computer Assisted Telephone Interview (CATI)	400	1	400	1.13	452

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with conducting industry surveys.

Dated: September 30, 1999.

**William K. Hubbard,**

Senior Associate Commissioner for Policy, Planning and Legislation.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Anti-Infective Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Anti-Infective Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 20 and 21, 1999, 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

*Contact:* Rhonda W. Stover, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530.

Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On the morning of October 20, 1999, the committee will discuss the development of antimicrobial drugs for the treatment of catheter-related bloodstream infections.

On the afternoon of October 20, 1999, the committee will discuss new drug applications (NDA's) 20-634 and 20-635, levofloxacin (Levaquin™, The R.W. Johnson Pharmaceutical Research Institute) for the treatment of community-acquired pneumonia due to penicillin-resistant *Streptococcal pneumoniae*.

On October 21, 1999, the committee will discuss NDA 21-085, moxifloxacin (Avelox™, Bayer Corp. Pharmaceutical Division), for the treatment of community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis, skin and skin-structure infections, and acute sinusitis.

*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 by October 13, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and between approximately 1 p.m. and 1:30 p.m. on October 20, 1999, and between approximately 8 a.m. and 8:30 a.m. on October 21, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 1999, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the October 20, 1999, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: September 29, 1999.

**Linda A. Suydam,**

Senior Associate Commissioner.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Consumer Round Table; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: "Consumer Round Table—Risk Management in a Diverse Society." This meeting will provide an opportunity for consumers to engage in an open dialogue with senior officials on how FDA ensures drug safety and manages and communicates the risks and benefits of drug products.