the results of that research. There is also the Med-Watch program as well as the Medical Device Reporting system to identify problems or trends associated with these devices. The agency believes the above survey, testing, and reporting programs provide adequate postmarket surveillance. The development of an FDA guidance as a special control will minimize the major sources of erroneous reporting associated with the fully automated short-term incubation cycle antimicrobial susceptibility device. Because special controls, in addition to general controls, would provide reasonable assurance of safety and effectiveness, the device should be classified into class II. There is sufficient information to establish special controls to provide such assurance.

X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. FDA Guidance Document, ''Review Criteria for Assessment of Antimicrobial Susceptibility Devices,'' 2000 revision.

2. NCCLS Approved Standard, M2 (most recent approved supplement), *Performance Standards for Antimicrobial Disk Susceptibility Tests,* Wayne, PA.

3. NCCLS Approved Standard, M7 (most recent approved supplement), *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,* Wayne, PA.

4. NCCLS Approved Standard, M100 (most recent approved supplement), *Performance Standards for Antimicrobial Susceptibility Testing,* Wayne, PA.

5. NCCLS Approved Standard, M23 (most recent approved supplement), *Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters,* Wayne, PA.

6. Transcript of the Microbiology Devices Panel Meeting, February 13, 1998.

XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Analysis of Impacts

FDA has examined the impacts of the notice under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96–354) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XIII. Request for Comments

Interested persons may, on or before June 7, 2000, submit to the Dockets Management Branch (address above) written comments regarding this document. 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. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 14, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–5523 Filed 3–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0109]

Draft Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices.'' This draft guidance is neither final nor is it in effect at this time. This guidance document would serve as a special control for the reclassification of fully automated short-term incubation cycle antimicrobial susceptibility devices from class III to class II.

DATES: Submit written comments concerning this guidance by June 7, 2000.

ADDRESS: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

On July 2, 1997, FDA received a petition from bioMerieux Vitek, Inc., requesting reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility devices from class III (premarket approval) to class II (special controls). Based on the petition, a meeting of the Microbiology Devices Panel (the Panel) was convened on February 13, 1998, to obtain the Panel's recommendation on the requested change in classification. The Panel unanimously recommended that fully automated short-term incubation cycle antimicrobial susceptibility devices be reclassified from class III to class II. This guidance document, which takes into consideration the Panel's recommendations and FDA's review experience, would be the special control for the reclassified device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on fully automated short-term incubation cycle antimicrobial susceptibility devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate device must demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternative control that provides equivalent assurances of safety and effectiveness.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive a copy of the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (631) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' will also be available at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, on or before June 7, 2000, submit to Docket Management Branch (address above) written comments regarding this draft guidance. 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–5524 Filed 3–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0357]

Draft Guidance for Industry on OTC Treatment of Herpes Labialis With Antiviral Agents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''OTC Treatment of Herpes Labialis with Antiviral Agents.'' Recent interest in marketing antiviral agents over-the-counter (OTC) to treat herpes labialis has raised public health concerns. This draft guidance summarizes the agency's current thinking on why it does not favor the OTC treatment of herpes labialis with antiherpes agents at this time. The guidance also describes issues that sponsors should consider before submitting a marketing application for an OTC antiviral product to treat herpes labialis.

DATES: Submit written comments on the draft guidance by May 8, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at hppt://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''OTC Treatment of Herpes Labialis with Antiviral Agents.'' This draft guidance summarizes the agency's current thinking on the OTC use of antiviral agents to treat herpes labialis. The agency believes that, until other safe