a. Extent to which the proposed method of tick control or anti-tick vaccines is scientifically valid and feasible. (20 points)

b. Scientific quality of the plan to evaluate the proposed prevention method (20 points)

c. Documented expertise of the applicant in tick control research or tick immunology, including publication of results in peer-reviewed scientific journals. (30 points)

d. Likelihood that the proposal will lead to a useful and practical prevention strategy that can be widely disseminated in community-based or other campaigns to prevent and control Lyme disease. (20 points)

e. Conformity of application narrative to stated requirements (no more that 10 single-spaced pages, no less than 12 point type. (5 points) Note: applications which are either more than 10 single-spaced pages, or use less than 12 point type, or both, will receive 0 points for this criterion).

f. Inclusion of Women, Ethnic, and Racial Groups Applicants should meet CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic populations for appropriate representation, (2) the proposed justification when representation is limited or absent, and (3) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits (5 points). If these provisions are not relevant to the proposed scope of work, state this and 5 points will be credited to the application.

g. Budget (Not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

h. Human Subjects (Not scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

i. Animal Research (Not scored)

If applicable, does the application adequately address the requirements for ethical research using animals?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports;

2. Financial Status Report, no more than 90 days after the end of the budget period; and

3. Final financial report and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

For descriptions of the following Other Requirements, see Attachment I. in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–3 Animal Subjects Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a)] and [42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.942.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page internet address—http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest, [01004].

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Henry E. Eggink, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone number: 770–488–2740, Email address: hbe7@cdc.gov. For program technical assistance, contact:

Edward B. Hayes, M.D., Joseph Piesman, D.Sc, Kathleen Orloski, D.V.M., M.S. or David Dennis, M.D., MPH, Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Fort Collins, CO 80522, Telephone number: 970–221–6400, Email address: jfp2@cdc.gov or ebh2@cdc.gov.

Dated: August 8, 2000.

John L. Williams,

Director, Procurement and Grants Office, Center for Disease Control and Prevention (CDC).

[FR Doc. 00–20499 Filed 8–11–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1401]

Draft Guidance for Industry on Administrative Procedures for CLIA Categorization; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ''Guidance for Administrative Procedures for CLIA Categorization.'' The Center for Devices and Radiological Health is issuing this draft guidance document to provide information to manufacturers on how to submit requests for complexity categorization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and how FDA will notify the manufacturer of the complexity categorization.

DATES: Submit written comments on the draft guidance document by November 13, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5diskette of the draft guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 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 draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Clara A. Sliva, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–827–0496.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2000, the responsibility for categorization of commercially marketed products under CLIA was transferred from the Centers for Disease Control and Prevention (CDC) to FDA. This allows manufacturers to submit premarket applications for products and requests for complexity categorization of these products under CLIA to one agency. This draft guidance document contains information on the administrative procedures that the manufacturers of in vitro diagnostic products will use to receive a complexity categorization under CLIA from FDA.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the administrative procedures for CLIA categorization of commercially marketed in vitro diagnostic products. 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.

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 guidance document is issued as Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance document entitled ''Guidance for the Administrative Procedures for CLIA Categorization'' 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 (1143) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so using the Internet. The Center for Devices and Radiological Health (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 with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance for Administrative Procedures for CLIA Categorization,'' 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. The draft guidance document entitled ''Guidance on the Administrative Procedures for CLIA Categorization'' will be available at http://www.fda.gov/cdrh//ode/guidance/1143.pdf

IV. Comments

Interested persons may, on or before November 13, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance 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. The draft 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: August 1, 2000.

Linda S. Kahan,

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

[FR Doc. 00–20464 Filed 8–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0053]

Guidance for Industry on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.'' This guidance document finalizes the agency's policy on how it intends to regulate third parties and hospitals engaged in reprocessing single-use devices (SUD's) for reuse. This guidance document sets forth FDA's priorities for premarket submission requirements, which will be based on the device's Code of Federal Regulations (CFR) classification (i.e., class I, II, and III).

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 3, 1999 (64 FR 59782), FDA published a proposed strategy on the reuse of SUD's. This proposal identified the steps under consideration in the development of the agency's SUD reprocessing policy. These steps were to: (1) Develop a list of commonly reused SUD's; (2) develop a list of factors to determine the degree of risk associated with reprocessing devices; (3) apply those factors to the list of commonly reprocessed SUD's and categorize them into three categories (high, moderate, and low); and (4) develop priorities for enforcement of premarket submission regulatory requirements for third party and hospital reprocessors, based on the category of risk.

In addition to publishing the proposed strategy document for public comment, FDA also sponsored a teleconference on November 10, 1999, and convened an open public meeting on December 14, 1999 (64 FR 63818,