Guidance for Industry and FDA Reviewers

Class II Special Control Guidance Document for Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Immunology Branch
Division of Clinical Laboratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dr. Peter Maxim, Center for Devices and Radiological Health, HFZ-440, 2098 Gaither Road, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Dr. Peter Maxim, (301) 594-1293.

Additional Copies

World Wide Web/CDRH/home page at http://www.fda.gov/cdrh/ode/guidance/1183.pdf or CDRH Facts on Demand at 1-800-899-0381 or (301) 827-0111, 1183 when prompted for the document shelf number.

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This document is intended to provide guidance. It represents the Agency's current thinking on the above. 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 requirements of the applicable statute, regulations, or both.

Background

On August 16, 2000, FDA classified Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) *in vitro* diagnostic devices from Class III designation to Class II. This guidance document describes a means by which anti-*S. cerevisiae* antibody (ASCA) devices may comply with the requirements of class II special controls. Designation of this guidance document as a special control means that manufacturers of anti-*S. cerevisiae* antibody devices, who follow the recommendations listed in this document before introducing their device into commercial distribution in the United States, will be able to market their device after they have submitted a premarket notification submission, referred to as a 510(k), and received a finding of "substantial equivalence" for their device. Manufacturers should comply with either the recommendations of this guidance or some alternate means that provide equivalent assurance of safety and effectiveness.

Scope

FDA identifies this generic type of device as an immunological device under 21 CFR §866.5785, product code NBT. This generic type of device, an anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) device is used for the semi-quantitative measurement of antibodies to *S. cerevisiae* (baker's and brewer's yeast) as an aid in the diagnosis of Crohn's disease.

Risks to Health

FDA has identified two risks to health associated with this type of device. These risks involve: 1) a falsely elevated result leading to a medical decision causing a patient to undergo needless therapy or an unnecessary change in treatment; or 2) a

falsely low result delaying recognition by the physician of the presence or progression of disease causing treatment to be delayed.

Special Controls Guidance

FDA believes the following controls, when combined with the general controls of the Food Drug and Cosmetic Act, will provide reasonable assurance of the safety and effectiveness of this type of device: labeling, design controls, and clinical information.

1. The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR §801.109.

2. Labeling in accordance with 21 CFR §809.10 (b). In addition, labeling should:

    a. support statements throughout the document with literature citations
    b. include an intended use statement with test methodology, specimen type, and whether the assay is qualitative or semi-quantitative
    c. include a summary of results from the clinical studies
    d. include quality control recommendations
    e. give an adequate description of the interpretation of results and expected results (incidence of ASCA in normal and diseased populations)
    f. include special limitations of the assay, e.g. restrictions in the pediatric population; the significance of a positive or negative result; use of the stated sample matrix only; etc.

3. Clinical information in the submission should demonstrate:

    a. the sensitivity in the target population
    b. specificity in other gastrointestinal disease and in healthy, non-diseased groups
    c. incidence of ASCA in all groups studied

4. Analytical/Laboratory performance studies should include:

    a. validation of the cut-off
    b. prevalence in the asymptomatic population
    c. assay specificity/interfering substances
    d. reproducibility at the cut-off and over the reportable range of the assay

e. antigen characterization
f. method and reagent description

5. Copies of current literature to support the use of ASCA in the diagnosis of Crohn's disease

For additional information refer to the following FDA guidance documents:

- Review Criteria for Assessment of Anti-Nuclear Antibodies (ANA) *in vitro* Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA) Immunodiffusion (IMD) and Enzyme-Linked Immunosorbent Assay (ELISA) at http://www.fda.gov/cdrh/ode/848.pdf.

- Review Criteria for Assessment of Rheumatoid Factor (RF) *in vitro* Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA) Enzyme-Linked Immunosorbent Assay (ELISA) Particle Agglutination Tests and Laser and Rate Nephelometry at http://www.fda.gov/cdrh/ode/rhuema.html.

- Review Criteria for *in vitro* Diagnostic Devices for the Assessment of Thyroid Autoantibodies Using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoassay (RIA), and Enzyme-Linked Immunosorbent Assay (ELISA) at http://www.fda.gov/cdrh/ode/odecl051.html.

These documents are available on the Internet as shown or from the Division of Small Manufacturers Assistance at its toll-free number (800) 899-0381 or (301) 827-0111

Premarket Notification

FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device, and therefore, the device type is not exempt from the premarket notification requirements. Thus, persons who intend to market a device of this type need to submit a premarket notification to FDA and receive agency clearance prior to marketing the device.