safety work, in a manner consistent with the maintenance of environmental protections. The Commission will further ensure that its personnel are available to respond to plant accidents or reportable incidents at LNG facilities, and address dam safety, public safety, and security incidents at jurisdictional hydropower projects. Alternate channels of communication will include measures to ensure that these activities can go forward unhindered.

(b) *Standards of conduct for transmission service providers.* During periods when the Commission's Continuity of Operations Plan is activated, a Transmission Provider affected by the same emergency affecting the Commission may, for 30 days, delay compliance with the requirement to report to the Commission each emergency that resulted in any deviation from the standards of conduct within 24 hours of such deviation. If the emergency prevents a Transmission Provider from posting information on the OASIS or Internet Web site, the Transmission Provide may, for 30 days, also delay compliance with the requirements of § 358.4(a)(2) of this chapter to post this information on the OASIS or Internet Web site, as applicable. Upon application by any such Transmission Provider, the Commission may extend these periods.

(c) *Tolling of time periods for Commission action.* The Commission tolls, for purposes of further consideration, the time period in which the Commission must act on the following matters if the time period during which the Commission would ordinarily be required to act closes during the period when the Continuity of Operations Plan is activated:

(1) 60-day period to act on requests for Exempt Wholesale Generator or Foreign Utility Company status;

(2) 90-day period for acting on requests for certification of qualifying facility status;

(3) 60-day period for acting on interlocking directorate applications;

(4) 60-day period for acting on Public Utility Holding Company Act exemptions and waivers;

(5) 180-period for acting on applications under § 203 of the FPA;

(6) 150-day period for acting on intrastate pipeline applications for approval of proposed rates;

(7) Period ending 60 days prior to the Electric Reliability Organization's (ERO) fiscal year for acting on the ERO's budget;

(8) 60-day period for acting on notifications that a Reliability Standard may conflict with a function, rule, order, tariff, rate schedule or agreement;

(9) 60-day period for acting on applications for review of a penalty imposed by the ERO for violation of a reliability standard;

(10) 45-day Protest period for protesting Prior Notice Filings, and the 30-day period for resolving and filing to withdraw such Protests;

(11) 30-day period for acting on requests for rehearing; and

(12) Time periods for acting on interlocutory appeals and certified questions.

(d) *Suspension of certain requirements.* During periods when the Commission's Continuity of Operations Plan is activated, requirements for the following filings, submissions, and notifications are suspended.

(1) Filings to comply with Commission orders, including orders issued by administrative law judges;

(2) Filings required to be made by a date certain under the Commission's regulations or orders;

(3) Motions to intervene and protests, and notices of intervention;

(4) Comments responding to proposed rulemakings or technical conferences;

(5) Responses to data requests;

(6) Self-reports of violations;

(7) Responses to staff audit reports;

(8) Contacts with the Commission's Enforcement Hotline;

(9) Accounting filings required by the Commission's Uniform Systems of Accounts; and

(10) Forms required to be filed by a date certain.

(e) *Acceptance and Suspension of Rate Filings.* When the date by which the Commission is required to act on filings made pursuant to section 4 of the Natural Gas Act, sections 205 of the Federal Power Act, and section 6(e) of the Interstate Commerce Act falls during periods when the Continuity of Operations Plan is activated, such filings shall be deemed to be accepted and suspended and made effective on the requested effective date, subject to refund and further order of the Commission.

(f) *Electric Reliability Organization Penalties.* If the date on which an Electric Reliability Organization imposes a penalty under Federal Power Act § 215 would take effect falls during a period when the COOP Plan is activated, review of such penalty by the Commission shall be deemed to be initiated and the penalty shall be stayed pending further action of the Commission.

(g) *Consistency of State action with reliability standard.* If the date by which a Commission determination under FPA § 215 as to whether a State action is inconsistent with a reliability standard is required to be made falls during a period when the COOP Plan is activated, the effectiveness of the State action will be deemed to be stayed pending further action by the Commission.

(h) *Suspension of Evidentiary Hearings.* During periods when the Continuity of Operations Plan is activated, all hearings, prehearing conferences, settlement conferences, and meetings before administrative law judges are suspended.

(i) *Enforcement Actions.* During periods when the Continuity of Operations Plan is activated, the Commission will not initiate an enforcement action under section 210(h)(2) of the Public Utility Regulatory Policies Act of 1978.

[FR Doc. E6–11990 Filed 7–26–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2006N–0276]

Medical Devices; Immunology and Microbiology Devices; Classification of Fecal Calprotectin Immunological Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying fecal calprotectin immunological test systems into class II (special controls). The special control that will apply to these devices is the guidance document entitled, ''Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems.'' The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for these devices.

DATES: This rule is effective August 28, 2006. The classification was effective April 26, 2006.

FOR FURTHER INFORMATION CONTACT: Deborah Moore, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither

Rd., Rockville, MD 20850, 240–276–0493.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on March 21, 2006, classifying the Genova Diagnostics, Inc. PhiCal™ Fecal Calprotectin Immunoassay in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On March 23, 2006, Genova Diagnostics, Inc. submitted a petition requesting classification of the PhiCal™ Fecal Calprotectin Immunoassay under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Genova Diagnostics, Inc. PhiCal™ Fecal Calprotectin Immunoassay can be classified into class II with the establishment of special controls. FDA believes that special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish special controls to provide such assurance.

The device is assigned the generic name ''fecal calprotectin immunological test system,'' and it is identified as an *in vitro* diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for *in vitro* diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

FDA has identified the risks to health associated with this type of device as inaccurate risk assessment and improper patient management. Failure of the system to perform as indicated, or error in interpretation of results, could lead to inaccurate risk assessment and improper management of patients with IBD. Specifically, a falsely low fecal calprotectin reading could result in a determination that the patient does not have IBD, which could delay appropriate treatment. A falsely high fecal calprotectin reading could result in a determination that the patient has IBD, which could lead to unnecessary evaluation and testing, or inappropriate treatment decisions. The use of assay results without consideration of other diagnostic testing and the total clinical picture could also pose a risk.

FDA believes that the class II special controls guidance document will aid in mitigating the potential risks to health by providing recommendations for the validation of performance characteristics, including software validation, control methods, reproducibility, and clinical studies. The guidance document also provides information on how to meet premarket [510(k)] submission requirements for the device. FDA believes that the special controls guidance document, in addition to general controls, addresses the risks to health identified in the previous paragraph and provides reasonable assurances of the safety and effectiveness of the device. Thus, on April, 26, 2006, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification at 21 CFR 866.5180.

Following the effective date of the final classification rule, manufacturers will need to address the issues covered in this special controls guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Thus, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, before marketing the device, which contains information about the fecal calprotectin immunological test system they intend to market.

II. What is the Environmental Impact of This Rule?

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

III. What is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 final rule is not a significant regulatory action as defined by 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. Because classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply with the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Thus, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) is not required. FDA concludes that the special controls guidance document contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled, ''Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems.'' The notice contains an analysis of the paperwork burden for the guidance.

VI. What References are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Genova Diagnostics, Inc., for reclassification of the PhiCal™ Fecal Calprotectin Immunoassay submitted March 22, 2006.

List of Subjects in 21 CFR Part 866

Medical devices.

■ Thus, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.5180 is added to subpart F to read as follows:

§ 866.5180 Fecal calprotectin immunological test system.

(a) *Identification.* A fecal calprotectin immunological test system is an *in vitro* diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for*in vitro* diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

(b) *Classification.* Class II (special controls). The special control for these devices is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems.'' For the availability of this guidance document, see § 866.1(e).

Dated: July 19, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–11975 Filed 7–26–06; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1990–0011; FRL–8202–8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Direct final notice of deletion of the Arctic Surplus Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA), Region 10, is publishing a direct final notice of deletion of the Arctic Surplus Site (Site), located in Fairbanks, Alaska, from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Alaska, through the Alaska Department of Environmental Conservation (ADEC) because EPA has determined that all appropriate response actions under CERCLA have been completed and, therefore, further remedial action pursuant to CERCLA is not appropriate.

DATES: This direct final deletion will be effective September 25, 2006 unless EPA receives adverse comments by August 28, 2006. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1990–0011, by one of the following methods:

- *http://www.regulations.gov*. Follow the on-line instruction for submitting comments.
- E-mail: *gusmano.jacques@epa.gov*.
- Fax: (907) 271–3424.