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.

• Mail: Jacques L. Gusmano, Remedial Project Manager, U.S. Environmental Protection Agency, Region 10, Alaska Operations Office, 222 West 7th Avenue, Suite 19, Anchorage, Alaska 99513.

• Hand Delivery: 222 West 7th Avenue, Suite 19, Anchorage, Alaska 99513. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SF–1990–0011. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index in the Deletion Docket Bibliography. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Deletion Docket materials are available electronically or in hard copy at the EPA's Region 10 Superfund Records Center, 1200 Sixth Avenue, Seattle, Washington 98101 and the Defense Reutilization & Marketing Office (Administrative Records) Building 5001, Mile Badger Road, Fairbanks, AK 99703 at (907) 353–1143. The Region 10 Superfund Records Center is open from 8 a.m. to 4:30 p.m. by appointment, Monday through Friday, excluding legal holidays. The Superfund Records Center telephone number is (206) 553–4494.

FOR FURTHER INFORMATION CONTACT:

Jacques L. Gusmano, Remedial Project Manager, U.S. Environmental Protection Agency, Region 10, Alaska Operations Office, 222 West 7th Avenue, Suite 19, Anchorage, Alaska 99513, phone: (907) 271–1271, fax: (907) 271–3424, e-mail: *gusmano.jacques@epa.gov*.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. NPL Deletion Criteria
III. Deletion Procedures
IV. Basis for Intended Site Deletion
V. Deletion Action

I. Introduction

EPA Region 10 is publishing this direct final notice of deletion of the Arctic Surplus Site, which is located in Fairbanks, Alaska from the NPL.

The EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective September 25, 2006 unless EPA receives adverse comments by August 28, 2006 on this document. If adverse comments are received within the 30-day public comment period for this document, EPA will publish a timely withdrawal of this direct final deletion before the effective date of the deletion and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Arctic Surplus Salvage Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that sites may be deleted from, or recategorized on the NPL, where no further response is appropriate. In making a determination to delete a site from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

(i) Responsible parties or other parties have implemented all appropriate response actions required;

(ii) All appropriate Fund-financed responses under CERCLA have been implemented, and no further action by responsible parties is appropriate; or

(iii) The Remedial Investigation has shown that the site poses no significant threat to public health or the environment and, therefore, remedial measures are not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants or contaminants remain at the site above levels that allow for unlimited use and unrestricted exposure, CERCLA section 121(c), 42 U.S.C. 9621(c) requires that a subsequent review of the site will be conducted at least every five years after the initiation of the remedial action at the deleted site to ensure that the site remains protective of public health and the environment. If new information becomes available which indicates a need for further action, EPA may initiate additional remedial actions. Whenever there is a significant release from a deleted site from the NPL, the site may be restored to the NPL without application of the Hazard Ranking System.

In the case of this site, the selected remedy is protective of human health and the environment; however, because the remedy leaves waste on site above levels that allow for unlimited use and unrestricted exposure, a review of the selected remedy will be conducted at least every five years from initiation of the remedial action.

III. Deletion Procedures

The following procedures were used for the intended deletion of Arctic Surplus:

(1) EPA Region 10 issued a Record of Decision (ROD) and an Explanation of Significant Differences (ESD) which documented the remedial action goals.

(2) The Defense Logistics Agency (DLA) issued a Remedial Action Report and a Final Closeout Report indicating remedial activities completed was issued by EPA.

(3) The State of Alaska has concurred with the proposed deletion decision.

(4) Concurrently with the publication of this direct final notice of deletion, a notice of the availability of the parallel notice of intent to delete published today in the ''Proposed Rules'' section of the **Federal Register** is being published in the *Fairbanks Daily News-Miner* and is being distributed to appropriate Federal, State, and local government officials and other interested parties; the newspaper notice announces the 30-day public comment period concerning the notice of intent to delete the Site from the NPL.

(5) All relevant documents have been compiled in the site deletion docket and made available in the local site information repositories. If adverse comments are received within the 30-day public comment period on this document, EPA will publish a timely notice of withdrawal of this direct final notice of deletion before its effective date. EPA will prepare a response to comments, and continue with the deletion process on the basis of the notice of intent to delete and the comments already received.

Deletion of the Site from the NPL does not in itself, create, alter or revoke any individual's rights or obligations. The NPL is designed primarily for informational purposes and to assist Agency management. As mentioned in Section II of this document, Sec. 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Intended Site Deletion

The following site summary provides the Agency's rationale for the proposal to delete this Site from the NPL.

Site Background and History

The Arctic Surplus Site, which consists of several land parcels, occupies 24.5 acres and is located on the northeast corner of Badger Road and the Old Richardson Highway, approximately six miles southeast of Fairbanks, Alaska. The western portion of the site was owned by the Department of Defense (DOD) and, from 1944 to 1956, a landfill used by the military was located on the parcel. Following its sale by DOD in 1959, the entire site was used as a salvage yard, resulting in the accumulation of a large amount of both salvageable and non-salvageable materials. The salvage yard activities that have impacted the site include:

- Lead battery recycling; batteries were stored and then cracked to collect lead for recycling;
- Draining oil from transformers, some of which contained polychlorinated biphenyls (PCBs);
- Burning spent transformer oils to fuel an incinerator used to reclaim copper from transformer coils and lead from batteries;
- Salvaging mechanized equipment, which may have caused fluids to leak;
- Accumulating spent ordnance and explosives-related scrap; and,
- Storing oils, chemicals, containerized gases, and other hazardous materials improperly.

Arctic Surplus was the subject of a Preliminary Assessment Report under the CERCLA dated June 29, 1987, and a Site Inspection in August/September 1988. The Site was proposed for the NPL on October 26, 1989, and was listed on August 30, 1990.

Since its identification as a CERCLA site, numerous investigations and removal actions have been performed to characterize the Site and address potential Site risks. Removal actions were completed during 1989, 1990, and 1991 by EPA and by the Defense Logistics Agency (DLA) for DOD. During 1989, the site was fenced, approximately 22,000 pounds of asbestos were removed, and approximately 75 gallons of the pesticide, chlordane, were stabilized and removed. During 1990, more extensive removal actions included the dismantling of an incinerator and removal and offsite disposal of associated ash and contaminated soil, and the removal and offsite disposal of approximately 13 cubic yards of PCB-contaminated soil, 315 cubic yards of lead-contaminated soil from ''battery-cracking,'' and approximately 160 cubic yards of chlordane-contaminated soil. The removal actions also included bulking and removal of containerized waste, removal of battery casings, draining and disposal of transformer oils, and capping of specific areas of contaminated soil. In 1991, another removal action was completed to investigate alleged buried hazardous wastes and delineate the extent of localized contamination. To facilitate the investigation, approximately 300 non-PCB transformers were moved and staged for removal.

The Remedial Investigation (RI) began in 1992 and was completed in 1994. In the RI, several potential source areas were identified including on the western half of the Site:

- Battery cracking areas;
- Buried materials, including the old military landfill;
- Incinerator area; and
- Transformer processing areas.

Additional potential source areas in other parts of the site were drum storage areas, and salvage and debris piles scattered all around the property. The two primary contaminants of concern (COCs) identified were lead and PCBs. Lead was identified at concentrations greater than 500 milligrams per kilogram (mg/kg) in surface soils over much of the western portion of the Site. It was also found at elevated concentrations in a limited number of samples of off-property soils, presumably transported by traffic, filling, and grading, or particulate transport from wind. PCB transformer oils were found in old transformers, drums, and oil-stained soils in several areas of the Site. During the 1990 removal actions, free product in containers was removed and heavily contaminated soils were excavated and removed from the Site. Subsequent analyses of the surface soil throughout much of the western part of the Site detected elevated concentrations of PCBs in surface soils, locally in excess of 100 mg/kg. Groundwater quality was studied in the RI as a potential contaminant pathway. One on-site monitoring well contained trichloroethylene (TCE) ranging from 6–14 ug/l (drinking water standard for TCE, 5 ug/l); this on-site well was located in the center of the property. No wells down gradient of this well, or any area residential wells had TCE concentrations above MCLs.

Selected Remedy

On September 28, 1995, the Regional Administrator signed a Record of Decision (ROD) selecting the following remedy:

- Relocation and sorting of salvage material and debris, which must be moved to provide access to the contaminated soil;
- Excavation and stockpiling of soil exceeding cleanup standards for treatment or disposal;
- Onsite treatment of soil exceeding 50 mg/kg PCBs by solvent extraction;
- Onsite treatment of soil exceeding the lead industrial cleanup standard of 1,000 mg/kg by stabilization/solidification.
- Offsite disposal of soil exceeding hot spot concentrations for pesticides of 21 mg/kg 4,4′-DDD, 15 mg/kg 4,4′-DDT, and 0.44 ug/kg 2,3,7,8-TCDD equivalence for dioxin/furans;
- Consolidation of treated soils into a containment area over the old closed military landfill;
- Capping of the containment area with a steep-sided cap to prevent future use; and

■ Implementation of institutional controls including long-term groundwater monitoring, and operation and maintenance of fences and the cap; restrictions to prevent use of groundwater, maintain industrial use, and prevent any unauthorized access or use of the capped area.

The design process to implement the ROD began in June 2002 with a reevaluation of the remedy selection. The design team consisted of representatives from EPA, ADEC, DLA, and DLA's consultants. The purpose of the reevaluation was to assess the current condition of the site relative to the ROD's goals and objectives, and to identify any improvements to the remediation process that could be implemented. The proposed treatment and cap design changes were evaluated by EPA and an Explanation of Significant Difference (ESD), signed on June 17, 2003, documented the changes to the original ROD. The changes to the ROD included in the ESD are:

■ Treatment of soil with PCB concentration between 10 and 50 mg/kg by solidification/stabilization and placement of the treated soil in the onsite containment area,

■ Offsite disposal of soil with PCBs greater than 50 mg/kg,

■ Capping the new waste containment area with a geosynthetic clay liner (GCL) instead of compacted silt,

■ Flattening the cap profile to allow for reuse of the land, and

■ Develop permanent institutional controls that will be attached to the property and transfer with the land.

Response Actions

EPA was negotiating an Agreement on Consent (AOC) with DOD when the remedial actions were begun. The final AOC was signed on December 11, 2003. The other PRPs did not participate in the cleanup actions. The cleanup activities that were conducted had two major objectives; to implement the ROD including the ESD changes; and to remove or demilitarize any ordnance or potentially explosive items. A Remedial Action Work Plan for the ROD which specified soil cleanup activities was issued in May 2003. Implementation of the soil remedy began in June 2003. The CERCLA remedial actions included:

■ Relocating, sorting, and decontamination of salvage material, ancillary scrap (transformers, compressed gas cylinders, etc.), and debris to access the contaminated soil beneath;

■ Excavation and stockpiling of contaminated soils with concentrations greater than 1,000 mg/kg lead or 10 mg/kg PCBs and off-property soils with concentrations greater than 400 mg/kg lead and/or 1 mg/kg PCBs;

■ Excavation and segregation of soil with concentrations of PCBs greater than 50 mg/kg; dioxin concentrations greater than 0.44 ug/kg; DDD concentrations greater than 21 mg/kg; and/or DDT concentrations greater than 15 mg/kg;

■ Shipment of dioxin-, DDT-, and DDD-contaminated soil and soil with greater than 50 mg/kg PCBs offsite for disposal;

■ Solidification/stabilization of contaminated soil containing lead at concentrations greater than 1,000 mg/kg, and soil with greater than 10 mg/kg but less than 50 mg/kg PCB;

■ Placement of stabilized soils into a containment area, which also encompasses the old existing landfill located in the southwestern section of the site; and

■ Capping the stabilized soil in the containment area and the existing landfill with a GCL cap.

Operation and Maintenance

Pursuant to the Administrative Order of Consent dated December 11, 2003, the long-term groundwater monitoring and the operations and maintenance (O&M) actions will be performed by DOD for the first five years, ending in September 2008. There are seven existing onsite groundwater monitoring wells that will be used for the long-term monitoring. There are three wells specifically downgradient of the new containment cell and one upgradient. The three other wells included in the long-term monitoring are along the northern property boundary. Provisions are included to extend this commitment as needed to maintain the site. The current O&M plan includes semi-annual groundwater monitoring and assessment of cap integrity.

Institutional Controls

The institutional controls relating to site access and land use restrictions were not part of the Administrative Order, but were made part of a State of Alaska action using a document called ''Conservation Easement,'' recorded on September 21, 2004. This type of enforceable document was used at Arctic Surplus because there was no Settlement Document, i.e., consent decree, signed by all of the PRPs, only an Administrative Order with DOD. The signatories to the Conservation Easement for Arctic Surplus are the property owners, who have agreed to the terms of the Conservation Easement. The administration and enforcement of this document for Arctic Surplus was delegated to ADEC by the Alaska Department of Natural Resources (ADNR) by a Management Right Assignment dated September 29, 2004. This Assignment has been filed by ADNR for the State of Alaska. This Conservation Easement document also includes EPA as a partner to ADEC for management and enforcement. ADEC has the responsibility to implement the Conservation Easement as an institutional control, and will provide EPA and the PRPs with a notice of any problems based on any site inspections.

Five-Year Review

Hazardous substances remain at the Site above levels that allow unlimited use and unrestricted exposure after the completion of the remedial action. Pursuant to CERCLA section 121(c) and as provided in the current guidance on Five-Year Reviews: OSWER Directive 9355.7–03B–P, Comprehensive Five-Year Review Guidance, dated June 2001, EPA must conduct a statutory Five-Year Review. The first Five-Year Review Report will be completed by December 22, 2008.

Community Involvement

EPA held nine public meetings, issued 13 fact sheets and published notices of three public comment periods in the **Federal Register** and in local newspapers. The meetings and fact sheets focused on CERCLA-required comment periods, informational meetings, enforcement actions, alternative analysis or schedule announcements, and public involvement sessions. Since completion of remedial actions there have been minimal public comments.

Applicable Deletion Criteria

One of the three criteria for deletion specifies that EPA may delete a site from the NPL if ''responsible parties have implemented all appropriate response actions required.'' EPA, with the concurrence of the State of Alaska, believe that this criterion for deletion has been met. There is no significant threat to human health or the environment and, therefore, no further remedial action is necessary.

State Concurrence

In a letter dated May 23, 2006, from the Alaska Department of Environmental Conservation (ADEC), ADEC concurs with the proposed deletion of the Arctic Surplus Site from the NPL.

V. Deletion Action

The EPA, with concurrence of the State of Alaska, has determined that all appropriate responses under CERCLA have been completed, and that no

further response actions, under CERCLA, other than O&M and five-year reviews, are necessary. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective September 25, 2006 unless EPA receives adverse comments by August 28, 2006. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will not take effect. In this case, EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: July 18, 2006.

Michelle Pirzadeh,

Acting Regional Administrator, Region 10.

■ For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601–9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR 1987 Comp., p. 193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended by removing the entry for ''Arctic Surplus, Fairbanks, Alaska.''

[FR Doc. E6–11809 Filed 7–26–06; 8:45 am]

BILLING CODE 6560–50–P