or an order declining the De Novo request under 860.289(b).

(b) A requester may supplement or amend a pending De Novo request to revise existing information or provide additional information.

(1) FDA may require additional information regarding the device that is necessary for FDA to complete the review of the De Novo request.

(2) Additional information submitted to FDA must include the reference number assigned to the original De Novo request and, if submitted on the requester's own initiative, the reason for submitting the additional information.

(c) Prior to granting or declining a De Novo request, FDA may inspect relevant facilities to help determine:

(1) That clinical or nonclinical data were collected in a manner that ensures that the data accurately represents the benefits and risks of the device; or

(2) That implementation of Quality System Regulation (part 820 of this chapter) requirements, in addition to other general controls and any specified special controls, provide adequate assurance that critical and/or novel manufacturing processes produce devices that meet specifications necessary to ensure reasonable assurance of safety and effectiveness.

§ 860.267 Withdrawal of a De Novo request.

(a) FDA will consider a De Novo request to have been withdrawn if:

(1) The requester fails to provide a complete response to a request for additional information pursuant to § 860.256(b)(1) within 180 days after the date FDA issues such request;

(2) The requester fails to provide a complete response to the deficiencies identified by FDA pursuant to § 860.245(c)(2) within 180 days of the date notification was issued by FDA;

(3) The requester does not permit an authorized FDA employee an opportunity to inspect the facilities, pursuant to § 860.256(c), at a reasonable time and in a reasonable manner, and to have access to copy and verify all records pertinent to the De Novo request; or

(4) The requester submits a written notice to FDA that the De Novo request has been withdrawn.

(b) If FDA considers a De Novo request to be withdrawn, the Agency will notify the requester. The notice will include the De Novo request reference number and the date FDA considered the De Novo request withdrawn.

§ 860.289 Granting or declining a De Novo request.

(a)(1) FDA will issue to the requester an order granting a De Novo request if none of the reasons in paragraph (b) of this section for declining the De Novo request applies.

(2) If FDA grants a De Novo request, FDA will subsequently publish in the **Federal Register** a notice of the classification order, including any special controls.

(b) FDA may issue written notice to the requester declining a De Novo request if the requester fails to follow the requirements of this part or if, upon the basis of the information submitted in the De Novo request or any other information before FDA, FDA determines:

(1) The device does not meet the criteria under section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act and § 860.3 for classification into class I or II;

(2) The De Novo request contains a false statement of material fact or there is a material omission;

(3) The device's labeling does not comply with the requirements in parts 801 and 809 of this chapter, as applicable;

(4) The product described in the De Novo request does not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act and is not a combination product as defined at § 3.2(e) of this chapter;

(5) The device is of a type which has already been approved in existing applications for premarket approval (PMAs) submitted under part 814 of this chapter;

(6) The device is of a type that has already been classified into class I, class II, or class III;

(7) An inspection of a relevant facility under § 860.256(c) results in a determination that general or general and special controls would not provide reasonable assurance of safety and effectiveness;

(8) A nonclinical laboratory study that is described in the De Novo request, and that is essential to show there is reasonable assurance of safety was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance is provided or, if a reason is provided, the practices used in conducting the study do not support the validity of the study;

(9) A clinical investigation described in the De Novo request involving human subjects that is subject to the institutional review board regulations in part 56 of this chapter, informed consent regulations in part 50 of this chapter, or GCP described in 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable;

(10) A clinical or nonclinical study necessary to demonstrate that general controls or general and special controls provide reasonable assurance of safety and effectiveness:

(i) Has not been completed per the study protocol, or

(ii) Deficiencies related to the investigation and identified in any request for additional information under § 860.256(b)(1) have not been adequately addressed; or

(11) After a De Novo request is accepted for review under § 860.245(b), the requester makes significant unsolicited changes to the device's:

(i) Indications for use; or

(ii) Technological characteristics.

(c) An order declining a De Novo request will inform the requester of the deficiencies in the De Novo request, including each applicable ground for declining the De Novo request.

(d) FDA will use the criteria specified in § 860.7 to determine the safety and effectiveness of a device in deciding whether to grant or decline a De Novo request. FDA may use information other than that submitted by the requester in making such determination.

■ 6. In part 860, remove all references to ''the act'' and add in their place ''the Federal Food, Drug, and Cosmetic Act''.

Dated: November 27, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–26378 Filed 12–4–18; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1987–0002; FRL–9987–15–Region 5]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Tomah Armory Landfill Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notification of intent.

SUMMARY: The Environmental Protection Agency (EPA) Region 5 is issuing a Notice of Intent to Delete the Tomah Armory Landfill Superfund Site (Tomah Armory Site), located in Tomah, Wisconsin, from the National Priorities

List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Wisconsin, through the Wisconsin Department of Natural Resources (WDNR), have determined that all appropriate response actions under CERCLA, other than operation and maintenance, monitoring and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments must be received by January 7, 2019.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1987–0002, by mail to Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the ''Rules and Regulations'' section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Randolph Cano, NPL Deletion Coordinator, U.S. Environmental Protection Agency Region 5 (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–6036, email: *cano.randolph@epa.gov.*

SUPPLEMENTARY INFORMATION: In the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing a direct final Notice of Deletion of the Tomah Armory Superfund Site without prior Notice of Intent to Delete because EPA views this as a noncontroversial revision and anticipates no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final Notice of Deletion, and those reasons are incorporated herein. If we receive no adverse comment(s) on this deletion action, we will not take further action on this Notice of Intent to Delete. If we receive adverse comment(s), we will withdraw the direct final Notice of Deletion, and it will not take effect. We will, as appropriate, address all public comments in a subsequent final Notice of Deletion based on this Notice of Intent to Delete. We will not institute a second comment period on this Notice of Intent to Delete. Any parties interested in commenting must do so at this time.

For additional information, see the direct final Notice of Deletion which is located in the ''Rules and Regulations'' section of this **Federal Register**.

List of Subjects in 40 CFR Part 300

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

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: October 30, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2018–26492 Filed 12–6–18; 8:45 am]

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