Section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act sets forth requirements for changes to be described in an annual report (minor changes). Under this section, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on the data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 6,929 annual reports will include documentation of certain manufacturing changes as required under section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act. FDA estimates that approximately 704 applicants will submit such information, and that it will take approximately 25 hours to prepare and submit to FDA the information for each annual report.

In the **Federal Register** of June 28, 1999 (64 FR 34608), FDA published a proposed rule to implement section 116 of the Modernization Act by revising current regulations at § 314.70 (21 CFR 314.70) on supplements and other changes to an approved application. In that same issue of the **Federal Register** (64 FR 34660), FDA published a notice of availability of a draft guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' On August 19, 1999, FDA held a public meeting to discuss and receive comments on the proposed regulations and the draft guidance (64 FR 42625, August 5, 1999).

The period for public comment on the proposed regulations closed on September 13, 1999, and FDA is currently reviewing the comments and preparing a final rule. The comment period for the draft guidance closed on August 27, 1999, and FDA has considered these comments when preparing the guidance that is the subject of this request.

In the **Federal Register** of November 23, 1999 (64 FR 65176), FDA requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement section 506A of the act. The use of normal information clearance procedures would likely result in the prevention or disruption of this collection of information because section 506A of the act takes effect on November 21, 1999. After November 20, 1999, and until final regulations are promulgated revising § 314.70, section 506A of the act will be the sole basis for FDA's regulation of postapproval manufacturing changes for products approved under NDA's or ANDA's. The guidance provides recommendations to holders of approved new drug and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product.

OMB has now approved the collection of information and has assigned OMB control number 0910–0431. This 6-month approval expires on May 31, 2000. By that date, FDA hopes to have completed the normal information clearance process initiated by this 60-day notice, and the agency hopes to obtain OMB approval for this collection of information for the usual 3-year period. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 99F–5523]

Alcide Corporation; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Alcide Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts.

DATES: Written comments on the petitioner's environmental assessment by February 7, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5)(21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 0A4705) has been filed by Alcide Corporation, 8561 154th Ave., NE, Redmond, WA 98052. The petition proposes to amend the food additive regulations in § 173.325 *Acidified sodium chlorite Solutions* (21 CFR 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before February 7, 2000, submit to the Dockets Management Branch (address above) written comments. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: December 9, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–238 Filed 1–5–00; 8:45 am]

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