Polyfibron's Liquid Photopolymer business. The proposed Order also requires that respondents provide incentives to certain employees identified by the acquirer as important to the continued competitiveness and viability of the Liquid Photopolymers business, to facilitate their transfer and the transfer of know-how to the acquirer.

The proposed Order to Maintain Assets requires that respondents preserve the Polyfibron Liquid Photopolymer business as a viable and competitive business until it is transferred to the Commission-approved acquirer. It includes an obligation on respondents to build and maintain a sufficient inventory of Liquid Photopolymers to ensure there is no shortage of supply during the period that the business is being transitioned to the Commission-approved acquirer, and obligations to maintain an adequate workforce.

Both the proposed Order and the Order to Maintain Assets include provisions designed to protect the Commission-approved acquirer during the transition period from the possibility that respondents might target customers on the customer lists being transferred to the Commission-approved acquirer. The provisions prohibit respondents from soliciting Liquid Photopolymer customers of Polyfibron for the transition period, which in any event is not to exceed ninety (90) days from the date the assets to be divested are transferred to the Commission-approved acquirer.

If, following receipt and review of public comments regarding the proposed Order, the Commission determines to disapprove the divestiture to Chemence, respondents are required to rescind the transaction with Chemence and divest Polyfibron's Liquid Photopolymers business, within three (3) months, to an acquirer that receives the prior approval of the Commission. The proposed Order also provides that if respondents fail to divest the Liquid Photopolymers business as required by the proposed Order, the Commission may appoint a Divestiture Trustee to divest the business along with any assets related to the business that are necessary to effect the purposes of the proposed Order.

Under the terms of the proposed Order, respondents are required to terminate their distribution agreements with BASF and Asahi. These provisions of the proposed Order are designed to remedy the foreseeable anticompetitive effects of maintaining the existing duopoly in the sale of Sheet Photopolymers in North America. Presently, DuPont and Polyfibron represent over ninety (90) percent of the sales of Sheet Photopolymers in North America. The investigation revealed that prices for Sheet Photopolymers in North America are considerably higher than prices for Sheet Photopolymers in other areas of the world where all of the major world players—DuPont, Polyfibron, BASF and Asahi—compete for business. Furthermore, the investigation revealed evidence of coordinated price activity in the sale of Sheet Photopolymers in North America among the two major firms. By requiring the respondents to terminate the distribution agreements with BASF and Asahi, the order frees BASF and Asahi to enter the North American market independently, and thereby to act as a competitive counterweight to DuPont and respondents.

Finally, the proposed Order requires that respondents cease and desist from inviting, creating, maintaining, adhering to, participating in, or enforcing any agreement with any producer of photopolymer products to allocate, divide or illegally restrict competition in the relevant markets. This provision of the proposed Order is designed to further enhance competition in the North American markets for Liquid Photopolymers and Sheet Photopolymers by ensuring that no potential entrant into these markets refrains from entering because of any illegal invitations from or arrangements with the respondents.

The proposed Order requires respondents to provide the Commission, within thirty (30) days of the date the Agreement is signed, with an initial report setting forth in detail the manner in which respondents will comply with the provisions relating to the divestiture of assets. The proposed Order further requires respondents to provide the Commission with a report of compliance with the Order within thirty (30) days following the date the Order becomes final and every thirty (30) days thereafter until they have complied with the divestiture provisions of the Order. Furthermore, the Order requires respondents to report annually to the Commission, for ten (10) years, regarding their compliance with the provisions of the Order relating to the Sheet Photopolymer distribution agreements and market allocation agreements.

The purpose of this analysis is to facilitate public comment on the proposed Order. This analysis is not intended to constitute an official interpretation of the Agreement or the proposed Order or in any way to modify the terms of the Agreement or the proposed Order.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 00–260 Filed 1–5–00; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in a guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' The guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 116 of the Food and Drug Administration Modernization Act (the Modernization Act), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

DATES: Submit written comments on the collection of information by March 6, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Changes to an Approved NDA or ANDA

On November 21, 1997, the President signed into law the Modernization Act (Public Law 105–115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved new drug and ANDAs', to new and abbreviated animal drug applications, and to license applications for biological products.

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. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

Section 116 of the Modernization Act amended the act by adding section 506A, which includes the following provisions:

1. A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (section 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

2. A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when ''validating the effects of the change'' (section 506A(c)(1) of the act).

3. A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug manufactured without the change; and (3) other changes determined by FDA by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug (section 506A(c)(2) of the act).

4. FDA may require submission of a supplemental application for drugs made with manufacturing changes that are not major (section 506A(d)(1)(B) of the act) and establish categories of manufacturing changes for which a supplemental application is required (section 506A(d)(1)(C) of the act). In such a case the applicant may begin distribution of the drug 30 days after FDA receives a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required (section 506A(d)(3)(B)(i) of the act). FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change (section 506A(d)(3)(B)(ii) of the act). If FDA disapproves a supplemental application, the agency may order the manufacturer to cease the distribution of drugs that have been made with the disapproved change (section 506A(d)(3)(B)(iii) of the act).

5. FDA may authorize applicants to distribute drugs without submitting a supplemental application (section 506A(d)(1)(A) of the act) and may establish categories of manufacturing changes that may be made without submitting a supplemental application (section 506A(d)(1)(C) of the act). The applicant is required to submit a report to FDA on such a change and the report is required to contain information the agency deems to be appropriate and information developed by the applicant when validating the effects of the change. FDA may also specify the date on which the report is to be submitted (section 506A(d)(2)(A) of the act). If during a single year an applicant makes more than one manufacturing change subject to an annual reporting requirement, FDA may authorize the applicant to submit a single report containing the required information for all the changes made during the year (annual report) (section 506A(d)(2)(B) of the act).

Section 506A of the act provides FDA with considerable flexibility to determine the information and filing mechanism required for the agency to assess the effect of manufacturing changes in the safety and effectiveness of the product. There is a corresponding need to retain such flexibility in the guidance on section 506A of the act to ensure that the least burdensome means for reporting changes are available. FDA believes that such flexibility will allow it to be responsive to increasing knowledge of and experience with certain types of changes and help ensure the efficacy and safety of the products involved. For example, a change that may currently be considered to have a substantial potential to have an adverse effect on the safety or effectiveness of the product may, at a later date, based on new information or advances in technology, be determined to have a

lesser potential to have such an adverse effect. Conversely, a change originally considered to have a minimal or moderate potential to have an adverse effect on the safety or effectiveness of the product may later, as a result of new information, be found to have an increased, substantial potential to adversely affect the product. The guidance enables the agency to respond more readily to knowledge gained from manufacturing experience, further research and data collection, and advances in technology. The guidance describes the agency's current interpretation of specific changes falling into the four filing categories. 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. The use of guidance documents allows FDA to more easily and quickly modify and update important information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Federal Food, Drug, and Cosmetic Act Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
506A(c)(1) and (c)(2) Prior Approval Supp.	594	3	1,744	120	209,280
506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) CBE in 30-days Supp.	594	5	2,754	80	220,320
506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(ii) CBE Supp.	486	1	486	80	38,880
506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) Annual Report	704	10	6,929	25	173,225
Total					641,705

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 506A(a)(1) and (b) of the act requires the holder of an approved application to validate the effects of a manufacturing change on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug before distributing a drug made with the change. Under section 506A(d)(3)(A) of the act, information developed by the applicant to validate the effects of the change regarding identity, strength, quality, purity, and potency is required to be submitted to FDA as part of the supplement or annual report. Thus, no separate estimates are provided for these sections in Table 1 of this document; estimates for validation requirements are included in the estimates for supplements and annual reports. The guidance does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

Section 506A(c)(1) and (c)(2) of the act sets forth requirements for changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes). Under this section, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a substantial 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. The applicant must obtain approval of a supplement from FDA prior to distribution of a product made using the change.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1,744 supplements will be submitted annually under section 506A(c)(1) and (c)(2) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 120 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act sets forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product made using the change (moderate changes). Under this section, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate 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. Distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA.

Based on the data concerning the number of supplements received by the agency, FDA estimates that approximately 2,754 supplements will be submitted annually under section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(3)(B)(ii) of the act, FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug upon receipt by the agency of a supplement for the change. Based on the data concerning the number of supplements received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

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.

[FR Doc. 00–236 Filed 1–5–00; 8:45 am]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F