the in-house technical capability to convert their operations or might find the prospective investments in sterile production technologies to be unattractive. Because each nonsterile product will require an annual report (21 CFR 314.81(b)(2)(iv), the number of annual responses for nonsterile products has increased to seven. Based on a review of FDA's past experience with applicants submitting supplemental applications under § 314.97, we estimate 160 hours to prepare a supplemental application. Therefore, due to the increased estimate of respondents, the total hours for the annual reporting burden for manufacturers of nonsterile products has increased from 800 hours in the proposed rule to 1,120 hours in the final rule. The agency's review of the estimated reporting burden for manufacturers of sterile products in the proposed rule and its experience with the annual reporting burden for manufacturers of sterile products supported the estimate provided in the proposed rule. Therefore, the estimated reporting burden for manufacturers of sterile products is the same as in the proposed rule.

Respondents to this information collection are businesses engaged in the manufacture of aqueous-based drug products for oral inhalation.

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

TABLE 1.–ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
314.97	7	1	7	160	1,120[2]
314.70	2	1	2	20	40[3]
Total					1,160

[1] There are no capital costs or operating and maintenance associated with this collection of information.
[2] Reporting burden for manufacturers of nonsterile products.
[3] Reporting burden for manufacturers of sterile products.

Because of the estimated increase from the proposed rule to the final rule in the number of respondents for nonsterile products, the number of recordkeepers in the recordkeeping burden of table 2 has increased by two from the proposed rule. FDA estimated a total of seven recordkeepers in the proposed rule and now estimates a total of nine recordkeepers as a result of new data collected by ERG. The proposed rule estimated 2 hours per record, and FDA's review of that estimate and its experience with the control and validation of microbiological contamination supports this proposed estimate. Therefore, the total number of hours for the recordkeeping burden has increased from 14 hours to 18 hours.

TABLE 2.–ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keepers	Total Annual Records	Hours per Record	Total Hours
211.113(b)	9	1	9	2	18
Total					18

In the **Federal Register** of September 18, 2000 (65 FR 56314), the agency requested comments on the proposed collections of information. No comments were received.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–48 Filed 1–2–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2081]

Troy Corp.; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Troy Corp. to indicate that the petitioner has proposed that the food additive regulations be amended to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, in pressure-sensitive adhesives, and in paper and paperboard intended to contact food.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 2, 1999 (64 FR 36021), FDA announced that a food additive petition (FAP 9B4678) had been filed by Troy Corp., c/o S. L. Graham & Associates, 1801 Peachtree Lane, Bowie, MD 20721. The petition proposed to amend the food additive regulations in § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in pressure sensitive adhesives.

Subsequent to the publication of the filing notice, the petition was amended to include a proposal to further amend the food additive regulations in 21 CFR 175.105 *Adhesives*, 21 CFR 176.170 *Components of paper and paperboard in contact with aqueous and fatty food*, 21 CFR 176.180 *Components of paper and paperboard in contact with dry foods*, and 21 CFR 178.3400 *Emulsifiers and/or surface active agents* to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, and in paper and paperboard intended to contact food.

Therefore, FDA is amending the filing notice of July 2, 1999, to indicate that the petitioner requests that the food

additive regulations be amended to provide for the safe use of butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt as a surface active agent in adhesives, in pressure sensitive adhesives, and in paper and paperboard intended to contact food.

The agency had previously determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 22, 2000.

Alan M. Rulis,

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

[FR Doc. 01–47 Filed 1–2–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2089–N]

RIN 0938–AK33

State Children's Health Insurance Program; Final Allotments to States, the District of Columbia, and U.S. Territories and Commonwealths for Fiscal Year 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice sets forth the final allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year (FY) 2001 under title XXI of the Social Security Act (the Act).

Established by section 4901 of the Balanced Budget Act of 1997, and amended by the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999, title XXI of the Act authorizes payment of Federal matching funds to States, the District of Columbia, and U.S. Territories and Commonwealths to initiate and expand health insurance coverage to uninsured, low-income children under a new State Children's Health Insurance Program (SCHIP). States may implement SCHIP through a separate State program under title XXI, an expansion of a State Medicaid program under title XIX, or a combination of both.

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FOR FURTHER INFORMATION CONTACT: Richard Strauss, (410) 786–2019.

SUPPLEMENTARY INFORMATION:

I. Purpose of This Notice

This notice sets forth the allotments available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for FY 2001 under title XXI of the Social Security Act (the Act).

Final allotments for a fiscal year are available to match expenditures under an approved State child health plan for 3 fiscal years, including the year for which the final allotment was provided. Federal funds appropriated for title XXI are limited, and the law specifies a formula to divide the total annual appropriation into individual allotments available for each State, the District of Columbia, and each U.S. Territory and Commonwealth with an approved child health plan.

Section 2104(b) of the Act indicates that ''the Secretary shall allot to each State * * * with a State child health plan approved under this title.'' This language requires States, the District of Columbia, and U.S. Territories and Commonwealths to have an approved child health plan for the fiscal year in order for the Secretary to provide an allotment for that fiscal year. All States, the District of Columbia, and U.S. Territories and Commonwealths had approved plans at the beginning of FY 2001. Therefore, the FY 2001 allotments contained in this notice pertain to all States, the District of Columbia, and U.S. Territories and Commonwealths.

II. Methodology for Determining Final Allotments for States, the District of Columbia, and U.S. Territories and Commonwealths

This notice specifies in the Table under section III, the final FY 2001 allotments available to individual States, the District of Columbia, and U.S. Territories and Commonwealths for child health assistance expenditures under approved State child health plans. As discussed below, the FY 2001 final allotments have been calculated to reflect the methodology for determining an allotment amount for each State, the District of Columbia, and each U.S. Territory and Commonwealth as prescribed by the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999.

Section 2104(a) of title XXI provides that, for purposes of providing allotments to the 50 States and the District of Columbia, the following amounts are appropriated: $4,295,000,000 for FY 1998; $4,275,000,000 for each FY 1999 through FY 2001; $3,150,000,000 for each FY 2002 through 2004; $4,050,000,000 for each FY 2005 through 2006; and $5,000,000,000 for FY 2007. However, under section 2104(c) of the Act, 0.25 percent of the total amount appropriated each year is available for allotment to the U.S. Territories and Commonwealths of Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Mariana Islands. The total amounts are allotted to the U.S. Territories and Commonwealths according to the following percentages: Puerto Rico, 91.6 percent; Guam, 3.5 percent; the Virgin Islands, 2.6 percent; American Samoa, 1.2 percent; and the Northern Mariana Islands, 1.1 percent.

For FY 2001, title XXI, as amended by the BBRA, provides an additional $34,200,000 for allotment to the U.S. Territories and Commonwealths. Therefore, the total amount available for allotment to the U.S. Territories and Commonwealths in FY 2001 is $44,887,500 (that is, $34,200,000 plus $10,687,500 (0.25 percent of the FY 2001 appropriation of $4,275,000,000)).

Furthermore, under sections 4921 and 4922 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), enacted on August 5, 1997, the total amount available for allotment to the 50 States and the District of Columbia is reduced by an additional total of $60,000,000; $30,000,000 to the Public Health Service for a special diabetes research program for children with Type I diabetes, and $30,000,000 for special diabetes