marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under § 207.30, establishments must update their product listing information by using Form FDA 2657 and/or Form FDA 2658 every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list, (2) all drug or biological products formerly listed for which commercial distribution has been discontinued, (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed, and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Form | 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| Form FDA 2656—Registration of Drug Establishment | 207.21<br>207.22<br>207.25<br>207.26<br>207.40 | 15,802 | .34 | 5,438 | 0.5 | 2,719 |
| Form FDA 2656e—Annual Update of Drug Establishment | 207.21<br>207.22<br>207.25<br>207.26<br>207.40 | 7,226 | 1 | 7,226 | 0.5 | 3,613 |
| Form FDA 2657—Drug Product Listing | 207.21<br>207.22<br>207.25<br>207.30<br>207.31<br>207.40 | 14,381 | 2.80 | 40,270 | 0.5 | 20,135 |
| Form FDA 2658—Registered Establishments' Report of Private Label Distributors | 207.21<br>207.22<br>207.25<br>207.30<br>207.31 | 6,221 | 2.14 | 13,289 | 0.5 | 6,645 |
| Total | | | | | | 33,112 |

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

Dated: October 25, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00–28135 Filed 11–01–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98F–1192]**

### Troy Corp.; Withdrawal of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 7B4546) proposing that the food additive regulations be amended to provide for the safe use of 3-iodo-2-propynyl butyl carbamate as a fungicidal additive for resinous and polymeric coatings 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 December 24, 1998 (63 FR 71295), FDA announced that a food additive petition (FAP 7B4546) 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 § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of 3-iodo-2-propynyl butyl carbamate as a fungicidal additive for resinous and polymeric coatings intended to contact food. Troy Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 11, 2000.

**Alan M. Rulis,**

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

[FR Doc. 00–28055 Filed 11–1–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–10017]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* New; *Title of Information Collection:* Follow-Up of Medicare+Choice DisenrolleesReceiving Fee-for-Service Inpatient Hospital Care; *Form No.:* HCFA–10017 (OMB# 0938–NEW); *Use:* This study will survey Medicare beneficiaries who had a fee-for-service hospital stay after choosing to leave a Medicare+Choice health plan. The purpose is to gather information about their reasons for disenrolling and to explore the link between the decision to disenroll and their subsequent fee-for-service care; *Frequency:* On occasion; *Affected Public:* Individuals or households; *Number of Respondents:* 600; *Total Annual Responses:* 600; *Total Annual Hours:* 650.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Date: October 24, 2000.

**John P. Burke, III,**

*Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 00–28170 Filed 11–1–00; 8:45 am]

**BILLING CODE 4120–03–U**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–R–0209 and HCFA–R–0245]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.11 and 484.20; *Form No.:* HCFA–R–0209 (OMB# 0938–0761); *Use:* The information collection requirements contained in the regulations state that HHAs must report data from the OASIS data set as a condition of participation for HHAs. Specifically, they provide guidelines for HHAs for the electronic transmission of the OASIS data set as well as responsibilities of the State agency or OASIS contractor in collecting and transmitting this information to HCFA. These requirements are necessary to establish a prospective payment system for HHAs and to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs; *Frequency:* As determined by HHA and monthly; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 7,500; *Total Annual Responses:* 7,500; *Total Annual Hours:* 911,313.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare and Medicaid Programs: Use of Outcome and Assessment Information Set (OASIS) as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.55; *Form No.:* HCFA–R–0245 (OMB# 0938–0760); *Use:* These information collection requirements are part of the existing conditions of participation that home health agencies (HHAs) must meet to participate in the Medicare program. Specifically, each patient must receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, the regulation requires that, as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, when evaluating adult, non-maternity patients. These changes are an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care; *Frequency:* Upon patient assessment; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 7,500; *Total Annual Responses:* 7,500; *Total Annual Hours:* 885,000.