Dated: December 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30280 Filed 12–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0641]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the agency's Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments.

DATES: Submit written or electronic comments on the collection of information by February 17, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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, including each proposed extension of an existing 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments (OMB Control Number 0910–0578)—Extension

The Operator's Manual contains information and recommendations for operators of retail and foodservice establishments who wish to develop and implement a voluntary food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles. Operators may decide to incorporate some or all of the principles presented in the manual into their existing food safety management systems. The recordkeeping practices discussed in the manual are voluntary and may include documenting certain activities, such as monitoring and verification, which the operator may or may not deem necessary to ensure food safety. The manual includes optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The Regulator's Manual contains recommendations for State, local, and tribal regulators on conducting risk-based inspections of retail and foodservice establishments, including recommendations about recordkeeping practices that can assist operators in preventing foodborne illness. These recommendations may lead to voluntary actions by operators based on consultation with regulators. For example, an operator may develop a risk control plan as an intervention strategy for controlling specific out-of-control foodborne illness risk factors identified during an inspection. Further, the manual contains recommendations to assist regulators when evaluating voluntary food safety management systems in retail and foodservice establishments. Such evaluations typically consist of the following two components: (1) Validation (assessing whether the establishment's voluntary food safety management system is adequate to control food safety hazards) and (2) verification (assessing whether the establishment is following its voluntary food safety management system). The manual includes a sample entitled ''Verification Inspection Checklist'' to assist regulators when conducting verification inspections of establishments with voluntary food safety management systems.

Types of operator records discussed in the manuals and listed in the following burden estimates include: (1) Food safety management systems (plans that delineate the formal procedures to follow to control all food safety hazards in an operation); (2) risk control plans (HACCP-based, goal-oriented plans for achieving active managerial control over specific out-of-control foodborne illness risk factors); (3) hazard analysis (written assessment of the significant food safety hazards associated with foods prepared in the establishment); (4) prerequisite programs (written policies or procedures, including but not limited to, standard operating procedures, training protocols, and buyer specifications that address maintenance of basic operational and sanitation conditions); (5) monitoring (records showing the observations or measurements that are made to help determine if critical limits are being met and maintained); (6) corrective action (records indicating the activities that are completed whenever a critical limit is not met); (7) ongoing verification (records showing the procedures that are followed to ensure that monitoring and other functions of the food safety management system are being implemented properly); and (8)

validation (records indicating that scientific and technical information is collected and evaluated to determine if the food safety management system, when properly implemented, effectively controls the hazards).

All recommendations in both manuals are voluntary. For simplicity and to avoid duplicate estimates for operator recordkeeping practices that are discussed in both manuals, the burden for all collection of information recommendations for retail and foodservice operators are estimated together in table 1 of this document, regardless of the manual in which they appear. Collection of information recommendations for regulators in the Regulator's Manual are listed separately in table 2 of this document.

Description of Respondents: The likely respondents to this collection of information are operators and regulators of retail and foodservice establishments.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR OPERATORS [1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Prerequisite Program Records	[2] 100,000	365	36,500,000	0.1	3,650,000
Monitoring Records	[2] 100,000	365	36,500,000	0.3	10,950,000
Corrective Action Records	[2] 100,000	365	36,500,000	0.1	3,650,000
Ongoing Verification Records (includes calibration records)	[2] 100,000	365	36,500,000	0.1	3,650,000
Validation Records	[2] 50,000	1	50,000	4	200,000
Annual Burden [3]:					22,100,000
Risk Control Plan	50,000	1	50,000	2	100,000
Monitoring Records	100,000	90	9,000,000	0.3	2,700,000
Corrective Action Records	100,000	90	9,000,000	0.1	900,000
Ongoing Verification Records (includes calibration records)	100,000	90	9,000,000	0.1	900,000
Annual Burden [4]					4,600,000
Total Annual Burden for Operators					26,700,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Annual burden.
[3] Burden for developing and implementing a food safety management system based on the Operator's Manual.
[4] Annual burden for developing and implementing a risk control plan based on the Regulator's Manual.

The burden for these activities may vary among retail and foodservice operators depending on the type and number of products involved, the complexity of an establishment's operation, the nature of the equipment or instruments required to monitor critical control points, and the extent to which an operator uses the Operator's Manual and/or the Regulator's Manual. The estimate does not include collections of information that are a usual and customary part of an operator's normal activities. FDA has established as a goal to have 50,000 (0.05 percent) of the approximately one million U.S. retail and foodservice operators implement the recommendations outlined in the 2 manuals. This target figure is used in calculating the burden in tables 1 and 2 of this document because the agency lacks data on how to base an estimate of how many retail and foodservice establishments are likely to use one or more of the manuals to voluntarily implement a comprehensive food safety management system based on HACCP principles or a risk control plan for out-of-control processes identified during an inspection. FDA's estimate of the total number of retail and foodservice establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute, and the National Restaurant Association, respectively.

The hour burden estimates in table 1 of this document for operators who follow the HACCP-based recommendations in the Operator's Manual are based on the estimated average annual information collection burden for mandatory HACCP rules, including seafood HACCP (60 FR 65096 at 65178; December 18, 1995) and juice HACCP (66 FR 6138 at 6202; January 19, 2001). FDA estimates that once the system is in place, the annual frequency of records is based on 365 operating days per year. Assuming there is one recordkeeper per shift of operation, the agency estimates that two recordkeepers per day would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the system. The agency further estimates that validation will be conducted once per year, based on menu or food list changes, changes in distributors, or changes in food preparation processes used. The validation will require a total of 4 labor hours.

The second set of estimates in table 1 of this document shows the annual burden for developing and implementing a risk control plan to control specific out-of-control foodborne illness risk factors identified during an inspection by a State, local, or tribal regulatory authority. If an operator decides to use a risk control plan as recommended in the Regulator's Manual, one person from the establishment is needed to work with the regulator to develop the written

plan. FDA estimates that two recordkeepers per day (one recordkeeper for each shift) would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the risk control plan. The estimated duration of implementation for a risk control plan is 90 days, which is the minimum recommended time to achieve long-term behavior change.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR REGULATORS [1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist)	50,000	1	50,000	16	800,000
Total Annual Burden for Regulators					800,000

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

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But, FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30278 Filed 12–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0617]

Determination That RUBRAMIN PC (Cyanocobalamin) Injection and Ten Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the eleven drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength andosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 6–799 for RUBRAMIN PC (cyanocobalamin)