upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: Agenda for this meeting will focus on priority issues related to the Mallinckrodt Site Profile Review. Specifically, the identification and clarification of specific issues to be included in the review; finalization of a timeline to complete the review; setting a time and location for future meetings and interactions; and initiating discussions of technical issues as appropriate.

The agenda is subject to change as priorities dictate.

In the event a member of the working group cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533–6825, fax (513) 533–6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 15, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–14380 Filed 7–20–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0083]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 22, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567—(OMB Control Number 0910–0338)—Extension

Under Section 351 of the Public Health Services Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to insure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 601.2(a) requires manufacturers of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under part 610 (21 CFR part 610) §§ 610.60, 610.61, and 610.62. The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires licensees to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires licensees to notify selling agents and distributors upon suspension of its license, and provide FDA with records of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved biologics license application must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires applicants to promptly revise all promotional labeling and advertising to make it consistent with certain labeling changes implemented. Section 601.12(a)(5) requires applicants to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under § 601.12(f)(4) in table 1 of this document or OMB control number 0910–0001 (expires May 31, 2008) because the required information is submitted with Forms FDA 2567 or 2253.

Section 601.12(b)(1) and (b)(3), (c)(1) and (c)(3), (c)(5), and (d)(1) and (d)(3) require applicants to follow specific procedures to inform FDA of each change, in the product, production process, quality controls, equipment, facilities, responsible personnel or labeling established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), applicants may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (b)(3) in table 1 of this document.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures to report labeling changes to FDA. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the safety or effectiveness of the product. Section 601.12(f)(4) requires

that applicants report to FDA advertising and promotional labeling and any changes. Section 601.45 requires that applicants of biological products for serious or life-threatening illnesses submit to the agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in parts 640, 660, and 680 (21 CFR parts 640, 660, and 680) that relate to information to be submitted in a license application or supplement for certain blood or allergenic products: Sections 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 660.51(a)(4), 680.1(b)(2)(iii), and 680.1(d). In the table 1 of this document, the burden associated with the information collection requirements in these regulations is included in the burden estimate for § 601.2 and/or § 601.12. A regulation may be listed under more than one paragraph of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products: Section 640.70(a) for source plasma; § 640.74(b)(3) and (b)(4) for source plasma liquid; § 640.84(a) and (c) for albumin; § 640.94(a) for plasma protein fraction; § 660.2(c) for antibody to Hepatitis B surface antigen; § 660.28(a) and (b) for blood grouping reagent; § 660.35(a), (c) through (g), and (i) through (m) for reagent red blood cells; § 660.45 for Hepatitis B surface antigen; and § 660.55(a) and (b) for anti-human globulin. The burden associated with the additional labeling requirements for submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.62 or § 809.10 (21 CFR 809.10). Therefore, the burden estimates for these regulations is included in the estimate under §§ 610.60 through 610.62 in table 1 of this document. The burden estimates associated with § 809.10 are approved under OMB control number 0910–0485 (expires June 30, 2008).

Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that applicants may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a). Section 601.27(c) provides that applicants may request a full or partial waiver of the requirements under § 601.27(a). The estimate for § 601.27(a) is included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.28 requires sponsors of licensed biological products to submit the information in § 601.28(a), (b), and (c) to the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, or on behalf of, the applicant.

Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to a patient or a potential patient for biological products approved under the subpart when human efficacy studies are not ethical or feasible (or based on efficacy studies conducted in animals alone). Section 601.93 provides that biological products approved under this subpart are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under this subpart to submit to the agency for consideration during the preapproval review period copies of all promotional materials including promotional labeling as well as advertisements. Under § 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under part 600 (21 CFR part 600) (OMB control number 0910–0308; pending extension of OMB approval). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB control number 0910–0308).

Section 610.11(g)(2) provides that a manufacturer of certain biological products may request an exemption from the general safety test (GST) requirements contained in this subpart. Under § 610.11(g)(2), FDA requires only those manufacturers of biological products requesting an exemption from the GST to submit additional information as part of a license application or supplement to an approved license application. Therefore, the burden estimate for § 610.11(g)(2) is included in the estimate under §§ 601.2(a) and 601.12(b) in table 1 of this document.

Section 610.67 requires certain biological products to comply with the bar code requirements in § 201.25 (21 CFR 201.25). Section 201.25 is approved under OMB control number 0910–0537 (expires February 28, 2007).

Section 680.1(c) requires that manufacturers update annually their license file with the list of source materials and the suppliers of the materials.

Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(d), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1 of this document.

Section 601.91(b)(2)(iii) provides that biological products approved under subpart H are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products.

In July 1997, FDA revised Form FDA 356h, ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use,'' to harmonize application

procedures between CBER and the CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for submissions to CDER using FDA Form 356h are reported under OMB control number 0910–0001.

Form FDA 2567 ''Transmittal of Labels and Circulars'' is used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by CBER. For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by CDER. In August of 1998, FDA revised and harmonized Form FDA 2253 so the form may be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure the submission is complete.

Under table 1 of this document, the number of respondents is based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received. Based on information obtained from CBER's database system, there are 306 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses are based on the estimated number of submissions (i.e., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under § 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification.

The number of respondents is based on the estimated annual number of suspensions of a biologic license.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. Based on information obtained from CBER's database system, there were an estimated 3,600 submissions of advertising and promotional labeling in fiscal year 2004. FDA estimates that approximately 15 percent of those submissions were received with Form FDA 2567 resulting in an estimated 540 submissions. The burden hours for the remaining submissions received using Form FDA 2253 are reported under OMB control number 0910–0376 (expires May 31, 2008).

Under §§ 601.91 through 601.94, FDA expects to receive very few applications of this nature; however, for calculation purposes, FDA is estimating the submission of one application annually. Under §§ 601.91(b)(3) and 601.94, FDA estimates 240 hours for a manufacturer of a new biological product to develop patient labeling, and to submit the appropriate information and promotional labeling to FDA. The majority of the burden for developing the patient labeling is included under the reporting requirements for § 601.94, therefore minimal burden is calculated for providing the guide to patients under § 601.91(b)(3).

There were also 3,540 amendments to an unapproved application or supplement and 23 resubmissions (total of 3,563 submissions) submitted using Form FDA 356h.

In the **Federal Register** of March 15, 2005 (70 FR 12693), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received. The comment was in response to whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility. The comment generally stated an opinion that the information collection program is not necessary, does not protect Americans, and is costly without justification. The comment did not request any action, nor did they provide data to support a change to the information collection requirements.

Information collection is a statutory requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA cannot abolish or modify the information collection requirements provided in the regulations (5 CFR 1320.3(c)) unless the statute is changed. Changing the statute is beyond FDA's authority and control.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.2(a), 610.60, 610.61, and 610.62[2]	2567/356h	14	2	28	860	24,080
601.5(a)	NA	16	3.13	50	.33	17

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.6(a)	NA	1	21	21	.33	7
601.12(a)(5)	NA	190	15.7	2,983	1	2,983
601.12(b)(1) and (b)(3)[3]	356h	190	4.75	903	80	72,240
601.12(c)(1) and (c)(3)[4]	356h	98	2.60	255	50	12,750
601.12(c)(5)[4]	356h	34	1.38	47	50	2,350
601.12(d)(1) and (d)(3)[5]	356h	166	1.37	227	22.5	5,107.5
601.12(e)	356h	14	1.43	20	120	2,400
601.12(f)(1)	2567	12	1	12	40	480
601.12(f)(2)	2567	10	1	10	20	200
601.12(f)(3)	2567	70	1.43	100	10	1,000
601.12(f)(4)[6] and 601.45	2567	15	36	540	10	5,400
601.25(b)(3)	NA	0	0	0	0	0
601.26(f)	NA	0	0	0	0	0
601.27(b)	NA	3	1	3	24	72
601.27(c)	NA	7	1	7	8	56
601.28(a)	NA	44	3.27	144	8	1,152
601.28(b)	NA	44	3.27	144	24	3,456
601.28(c)	NA	44	3.27	144	1.5	216
601.91(b)(3) and 601.94	NA	1	1	1	240	240
610.67	NA	174	31	5,400	24	129,600
680.1(c)	NA	10	1	10	2	20
Amendments/Resubmissions	356h	306	11.6	3,563	20	71,260
Total						335,086.5

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

[2] The reporting requirements under §§ 601.27(a), 601.33, 601.34, 601.35, 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a). The reporting requirements under §§ 640.70(a); 640.74(b)(3) and (b)(4); 640.84(a) and (c); 640.94(a); 660.2(c); 660.28(a) and (b); 660.35(a), (c) through (g), and (i) through (m); 660.45; and 660.55(a) and (b) are included under §§ 610.60 through 610.62.

[3] The reporting requirements under §§ 600.15(b), 601.12(a)(2), 601.12(b) (4), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), and 680.1(d) are included in the estimate under § 601.12(b)(1) and (b)(3).

[4] The reporting requirements under §§ 601.12(a)(2), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are also included in the estimate under § 601.12(c)(1) and (c)(3) or (c)(5).

[5] The reporting requirements under § 601.12(a)(2) are also included in the estimates under § 601.12(d)(1) and (d)(3).

[6] The reporting requirements under § 601.12(a)(4) are included in the estimates under § 601.12(f)(4) or OMB control number 0910–0001 since the required information is submitted with Form FDA 2567 or 2253.

Under table 2 of this document, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
601.91(b)(2)(iii)	1	1	1	1	1

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

Dated: July 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14330 Filed 7–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0274]

Draft Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft manuals entitled ''Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments'' (the ''Operator's Manual'') and ''Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems'' (the ''Regulator's Manual''). The Operator's Manual presents FDA's best advice to retail and foodservice operators for voluntarily implementing food safety management systems based on hazard analysis and critical control point (HACCP) principles to reduce the occurrence of foodborne illness risk factors. The Regulator's Manual is intended to assist State, local, and tribal regulatory authorities in identifying and assessing control of foodborne illness risk factors during routine inspections of retail and foodservice establishments by providing a risk-based inspection methodology.

DATES: Submit written or electronic comments concerning the draft manuals and their recommendations for collection of information by September 19, 2005.

ADDRESSES: Submit written comments concerning the draft manuals and their recommendations for collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft manuals and their recommendations for collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft manuals to Margaret Boone, Center for Food Safety and Applied Nutrition (HFS–625), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1559. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft manuals and received comments.

FOR FURTHER INFORMATION CONTACT: Alan Tart, Office of Regulatory Affairs, Southeast Regional Office, State Cooperative Programs (HFR–SE670), Food and Drug Administration, 60 8th St., NE., Atlanta, GA 30309, 404–253–1267.

SUPPLEMENTARY INFORMATION:

I. Background

While the responsibility for regulating retail and foodservice establishments lies primarily with State, local, and tribal jurisdictions, FDA provides assistance to these jurisdictions through multiple means, including but not limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The Centers for Disease Control and Prevention has identified the major contributing factors associated with foodborne illness outbreaks. Five of these contributing factors directly relate to retail and foodservice establishments and are called ''foodborne illness risk factors'' by FDA. Food safety management systems based on HACCP principles are designed to reduce the occurrence of these risk factors through preventive controls. For industry, the rationale for developing and implementing a food safety management system based on HACCP principles is to ensure that final products are not contaminated with agents that could cause foodborne illness or injury. In an effort to assist State, local, and tribal regulators and the retail and foodservice entities they regulate, FDA has developed two draft manuals for the voluntary use of HACCP principles in retail and foodservice establishments.

The Operator's Manual provides operators of retail and foodservice establishments with a step-by-step scheme for designing and voluntarily implementing food safety management systems based on HACCP principles. By voluntarily implementing food safety management systems, active managerial control of foodborne illness risk factors can be achieved. Any operator of a retail or foodservice establishment is encouraged to voluntarily utilize the methods and procedures presented in the draft manual.

The Regulator's Manual provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles. In addition, the draft manual details intervention strategies that can be developed with retail and foodservice operators to reduce the occurrence of foodborne illness risk factors. It also provides a methodology for evaluating voluntarily-implemented food safety management systems, if invited to do so, by retail or foodservice operators.

Comments received from the Conference for Food Protection (CFP) have been incorporated into the draft manuals. The CFP is composed of regulators, industry, academia, professional organizations, and consumers. Its purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety. In 2004, CFP endorsed both draft manuals with a recommendation that both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs.

The utilization of voluntary food safety management systems by industry, as well as the incorporation of a risk-based methodology into regulatory inspection programs, are important elements in reaching the goals established by the President's Council on Food Safety and also FDA program goals.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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