processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

In the **Federal Register** of November 20, 2013 (78 FR 69689), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.6(c) and 120.12(a)(1) and (b); Require written monitoring and correction records for Sanitation Standard Operating Procedures (SSOPs).	1,875	365	684,375	0.1 (8 minutes)	68,438
120.7 and 120.12(a)(2), (b) and (c); Require written hazard analysis of food hazards.	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b); Require a recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.	1,450	14,600	21,170,000	0.01 (1 minute)	211,700
120.10(c) and 120.12(a)(4)(ii) and (b); Require that all corrective actions taken in response to a deviation from a critical limit be documented.	1,840	12	22,080	0.1 (8 minutes)	2,208
120.11(a)(1)(iv) and (a)(2), 120.12(a)(5); Require records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures.	1,840	52	95,680	0.1 (8 minutes)	9,568
120.11(b) and 120.12(a)(5) and (b); Require that every processor record the validation that the HACCP plan is adequate to control food hazards that are likely to occur.	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d); Require that importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120.	308	1	308	4	1,232
120.11(c) and 120.12(a)(5) and (b); Require documentation of revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have an HACCP plan because the original hazard analysis did not reveal hazards likely to occur).	1,840	1	1,840	4	7,360
Total					358,466

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

Table 1 provides our estimate of the total annual recordkeeping burden of our regulations in part 120. We base our estimate of the average burden per recordkeeping on our experience with the application of HACCP principles in food processing. We base our estimate of the number of recordkeepers on our estimate of the total number of juice manufacturing plants affected by the regulations (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers). These estimates assume that every processor will prepare sanitary standard operating procedures and an HACCP plan and maintain the associated monitoring records, and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have an HACCP plan under these regulations.

Dated: January 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01462 Filed 1–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0383]

Agency Information Collection Activities: Proposed Collection; Comment Request; Radioactive Drug Research Committees

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 contained in regulations governing the use of radioactive drugs for basic informational research.

DATES: Submit either electronic or written comments on the collection of information by March 28, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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.

Radioactive Drug Research Committees—(OMB Control Number 0910–0053)—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees (RDRC) and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each RDRC shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the RDRC, using Form FDA 2914, and a summary of each study conducted during the preceding year, using Form FDA 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the RDRC all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application (IND) under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual RDRC, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR sections/forms	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
361.1(c)(3)&(4); Form FDA 2914	69	1	69	1	69
361.1(c)(3); Form FDA 2915	48	10	480	3.5	1,680
361.1(d)(8)	10	5	50	0.5 (30 minutes)	25
Total					1,774

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
361.1(c)(2)	69	4	276	10	2,760
361.1(d)(5)	35	18	630	0.75 (45 minutes)	472.5
Total					3,232.5

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

Dated: January 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01463 Filed 1–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1432]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables

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 (the PRA).

DATES: Fax written comments on the collection of information by February 26, 2014.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0609. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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.

Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables (OMB Control Number 0910–0609)—Extension

Fresh-cut fruits and vegetables are fruits and vegetables that have been processed by peeling, slicing, chopping, shredding, coring, trimming, or mashing, with or without washing or other treatment, prior to being packaged for consumption. The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the produce in transmitting foodborne illness. Factors such as the high degree of handling and mixing of the product, the release of cellular fluids during cutting or mashing, the high moisture content of the product, the absence of a step lethal to pathogens, and the potential for temperature abuse in the processing, storage, transport, and retail display all increase the potential for pathogens to survive and grow in fresh-cut produce.

Sections 301 and 402 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331 and 342) prohibits the distribution of adulterated food in interstate commerce. In response to the increased consumption of fresh-cut fruits and vegetables and the potential for foodborne illness associated with these products, we recognize the need for guidance specific to the processing of fresh-cut fruits and vegetables. The guidance document entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,'' which is available at *http://www.fda.gov/FoodGuidances,* provides our recommendations to fresh-cut produce processors about how to avoid contamination of their product with pathogens. The guidance is in addition to the good manufacturing practice (GMP) regulations found in part 110 (21 CFR part 110). The guidance is intended to assist fresh-cut produce processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form. Accordingly, we encourage fresh-cut produce processors to adopt the general recommendations in the guidance and to tailor practices to their individual operations.

The guidance provides information and recommended procedures designed to help fresh-cut produce processors minimize microbial food safety hazards. The recommended procedures contained in the guidance are voluntary. Both FDA and fresh-cut produce processors will use and benefit from the information collected.