their commitment to the success of this program. The WHO represents a key stakeholder in the implementation of the program; providing unique functions, technical and scientific expertise, and capabilities that no other organization in the world has.

Additional Information: The agency program contact is Dr. Michael Perdue, whom can be contacted at (202) 260–0966 or *Michael.Perdue@hhs.gov.*

Dated: August 3, 2010.

Nicole Lurie,

Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.

[FR Doc. 2010–19861 Filed 8–10–10; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Stem Cell Therapeutic Outcomes Database (OMB No. 0915–0310)—Extension

The Stem Cell Therapeutic and Research Act of 2005 provides for the collection and maintenance of human cord blood stem cells for the treatment of patients and research. The Health Resources and Services Administration's (HRSA) Healthcare Systems Bureau (HSB) has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain recordkeeping and reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to the Department of Health and Human Services (HHS). The Act requires the Secretary of HHS to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data are collected from transplant centers in a manner similar to the data collection activities conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR) and are used for ongoing analysis of transplant outcomes. HRSA uses the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation, and to provide the Secretary with an annual report of transplant center-specific survival data. The burden table for the year 2011 shows there will be approximately 12,800 annual follow-up assessments due for the Blood Stem Cell Transplantation Program's Stem Cell Therapeutic Outcomes Database. The 2007 30-Day Federal Register notice included total burden hours of 32,040 and 225 respondents. The burden table below includes 38,700 total burden hours and 200 respondents. The increase in burden is due to an increase in the annual number of transplants. The number of respondents has decreased due to some centers no longer performing unrelated stem cell transplants and some centers are no longer in business.

The estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per Response	Total burden hours
Baseline Pre-TED (Transplant Essential Data)	200	30	6,000	0.85	5,100
Product Forms (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	20	4,000	1.5	6,000
100-Day Post-TED	200	30	6,000	0.85	5,100
6-Month Post-TED	200	25	5,000	1.00	5,000
12-Month Post-TED	200	23.5	4,700	1.00	4,700
Annual Post-TED	200	64	12,800	1.00	12,800
Total	200		38,500		38,700

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: August 5, 2010.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2010–19752 Filed 8–10–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0411]

Agency Information Collection Activities; Proposed Collection; 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 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 in the guidance document entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables."

DATES: Submit either electronic or written comments on the collection of information by October 12, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

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 enhance the potential for pathogens to survive and grow in fresh-cut produce.

The Federal Food, Drug, and Cosmetic Act (the act) prohibits the distribution of adulterated food in interstate commerce (21 U.S.C. 331 and 342). In response to the increased consumption of fresh-cut fruits and vegetables and the potential for foodborne illness associated with these products, FDA recognizes 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 FDA's recommendations to fresh-cut produce processors about how to avoid contamination of their product with pathogens. This guidance is in addition to the good manufacturing practices (GMPs) provided in part 110 of FDA's regulations (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, FDA encourages 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.

Two general recommendations in the guidance are for operators to develop and implement both a written Standard Operating Procedures (SOPs) plan and a Sanitary Standard Operation Procedures (SSOPs) plan. SOPs and SSOPs are important components to properly implemented and monitored GMPs that are required for processed food operations under part 110. Other recommended programs that require documentation and recordkeeping are recall and traceback programs. In the event of a food safety concern, processors who adopt these recommended programs will be prepared to recall products from the market place or be able to trace back fresh produce, which might be implicated in a foodborne illness outbreak, to its source. Fresh-cut produce processors are also asked to consider the application of Hazards Analysis and Critical Control Point (HACCP) principles or comparable preventive control programs to the processing of fruits and vegetables. FDA, other Federal and state food agencies, industry, and food establishments have found such preventive control programs, when properly designed and maintained by the establishment's personnel, to be valuable in managing the safety of food products.

FDA's fresh-cut guidance represents the agency's recommendations to industry based on the current state of science. Following the recommendations set forth in the fresh-cut guidance is the choice of each individual fresh-cut operation, plant, or processor. FDA estimates the burden of this guidance on industry by assuming that those in the fresh-cut industry who do not currently follow the recommendations put forth in the guidance will find it of value to do so. Therefore, the estimates of the burden associated with the issuance of this guidance represent the upper bound estimate of burden, the burden if every fresh-cut plant, processor, or operation that does not follow the recommendations of the guidance should choose to do so.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
SOP and SSOP: Maintenance	122	3,315	404,430	0.067	27,097
Traceback Development	10	1	10	20	200
Traceback Maintenance	290	1	290	40	11,600
Preventive Control Program Comparable to a HACCP System: System Development	10	1	10	100	1,000
Preventive Control Program Comparable to a HACCP System: System Implementation	145	510	73,950	0.067	4,955
Preventive Control Program Comparable to a HACCP System: Implementation Review	145	4	580	4	2,320
Annual Burden Hours					47,172

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

Industry Profile

Estimates of the paperwork burden to the fresh-cut industry are based on information received from a fresh-cut processor who has developed and maintained these programs and information from a fresh-cut produce industry trade association. Because of the small number of fresh-cut processors, the agency is able to extrapolate data from industry programs to calculate the total estimated upper bound burdens. (See table 1 of this document.)

The burden to industry of developing and maintaining the activities recommended in FDA's fresh-cut guidance will vary considerably among fresh-cut processors, depending on the type and number of products involved, the sophistication of the equipment or instruments (e.g., those that automatically monitor and record food safety controls), and the type of controls monitored under any individual preventive control program, such as critical control points (CCPs) monitored under a HACCP program.

In 2007, FDA estimated that there were 250 fresh-cut plants in operation in the United States, and that approximately 10 new firms enter the fresh-cut industry each year (72 FR 11364 at 11366). Using these figures, we estimate that in 2010 there are 280 fresh-cut plants in operation and that approximately 10 new firms will enter the fresh-cut industry each year, over the next 3 years. Many of the existing firms in the fresh-cut industry already make use of current good manufacturing practices-related, recall, HACCP, and other activities. FDA estimates that the burden of this fresh-cut guidance will fall on both existing and new firms entering the industry who may follow the recommendations in the guidance.

SOPs and SSOPs

Two general recommendations in this guidance are for operators to develop and implement both a SOPs plan and a written SSOPs plan. SOPs describe in writing the performance of the day-to-day operations of a processing plant. Examples of activities that would fall under SOPs would be developing written specifications for agricultural inputs, ingredients, and packaging materials; production steps for the processing and packaging operations; instructions for packaging and storage activities; and procedures for equipment maintenance, calibration, and replacement and facility maintenance and upkeep; and maintaining SOP records on product processing and distribution activities.

SSOPs provide written instructions or procedures for sanitary practices developed for each specific sanitation activity in and around the facility. Sanitation activities include procedures for cleaning equipment, food-contact surfaces, and plant facilities; chemical use and storage; cleaning equipment maintenance, use, and storage; pest control; and maintaining SSOP records for the activities. From communication with the fresh-cut industry, we know that existing fresh-cut processors already have developed SOPs and SSOPs. We therefore consider the development of SOPs and SSOPs to be "usual and customary" for manufacturers and processors in the fresh-cut industry. (See 5 CFR 1320.3(b)(2).) Thus, we do not calculate this burden for existing firms or new firms entering this industry.

FDA recommends that facilities not only develop but also maintain SOPs and SSOPs. Implementation and maintenance of SOPs and SSOPs include maintaining daily records for each of the firm's operational days for the following activities: Inspection of incoming ingredients, such as the fresh produce and packaging material; facility and production sanitation inspections; equipment maintenance, sanitation, and visual safety inspections; equipment calibration, e.g., checking pH meters; facility and premises pest control audits; temperature controls during processing and in storage areas; and audits of ingredients, food contact surfaces, and equipment for microbiological contamination. Of the 280 fresh-cut processors, we estimate that well over half have SOP and SSOP maintenance programs in place. Therefore, for purposes of estimating the annual recordkeeping burden for SOP and SSOP maintenance programs, the agency assumed that 40 percent of the existing processors, or 112 firms, and the 10 new firms do not have SOP and SSOP maintenance programs in place. FDA estimates the recordkeeping burden for SOP and SSOP maintenance programs by assuming that these 122 firms will choose to implement such a maintenance strategy as a result of the recommendations in the fresh-cut guidance document.

A typical fresh-cut processing plant operates about 255 days per year. For an 8-hour shift, assuming the ingredients are received twice during that time, under the recommendations in the

guidance, there would be about 13 records kept (2 for inspecting incoming ingredients; 2 for inspecting the facility and production areas once every 4 hours; 3 records for equipment (maintenance, sanitation, and visual inspections for defects); one for calibrating equipment; 2 temperature recording audits (1 time for each of the 2 processing runs); and 3 microbiological audits (ingredients, food contact surfaces, and equipment)). Therefore, the annual frequency of recordkeeping for SOPs and SSOPs is calculated to be 3,315 times (255 x 13) per year per firm; 122 firms will be performing these activities to generate a total 404,430 records (3,315 x 122) annually, assuming all firms choose to follow the recommendations on keeping records.

The total time to record observations for SOP and SSOP maintenance is estimated to take 4 minutes or 0.067 hours per record, and the number of records maintained is 404,430. Therefore, the total annual burden in hours for 122 processors to maintain their SOP and SSOP records is approximately 27,097 hours (404,430 x 0.067). The maintenance burden for these 122 firms, along with the annual maintenance burden of audits or testing, is estimated in row 1 of table 1 of this document. Again, these figures assume that all firms choose to follow the recommendations on recording observations.

Recall and Traceback

We recommend that fresh-cut processors establish and maintain written traceback procedures to respond to food safety hazard problems when they arise and establish and maintain a written contingency plan for use in initiating and effecting a recall. In order to facilitate tracebacks and recalls, we recommend that processors establish a program that documents and tracks fresh-cut products back to the source of their raw ingredients, and keep records of product identity and specifications, the product in inventory, and where, when, to whom, and how much of the product is shipped.

Traceback programs are used for those times when a food safety problem has been identified or a product has been implicated in a foodborne illness outbreak. The burden to develop a traceback program is a one-time activity estimated to take approximately 20 hours. In 2007, we previously estimated that firms in the industry would choose to begin a traceback program after the guidance was made available and estimated that the 250 existing fresh-cut firms and the 10 new businesses expected to enter the industry annually from 2007 to 2010 would spend 5,200 hours (250 x 20) on this activity. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry annually in the next 3 years. We estimate that the 10 new firms will spend 20 hours each preparing a traceback program, for a total of 200 hours (10 x 20). The burden estimate of developing a traceback program is shown in row 2 of table 1 of this document.

Traceback program adjustments or revisions may, or may not, be needed annually. Firms may test their traceback programs yearly to see if adjustments are needed to maintain traceback capabilities. Evaluating and updating traceback programs is estimated to take 40 hours to complete. The annual burden of maintaining a traceback program is estimated for the 280 existing firms in the industry plus the 10 firms new to the industry that may decide to implement this type of program. Assuming that each firm completes this exercise once a year, the total maintenance burden of traceback programs is 11,600 hours yearly (290 x 40). This burden estimate is shown in row 3 of table 1 of this document.

The fresh-cut guidance refers to previously approved collections of information found in FDA regulations. The recommendations in this document regarding establishing and maintaining a recall plan, as provided in 21 CFR 7.59, have been approved under OMB control number 0910–0249. Therefore, FDA is not calculating a new paperwork burden for recall plans.

Preventative Control Program

When properly designed and maintained by the establishment's personnel, a preventive control program is a valuable program for managing the safety of food products. A common preventive control program used by the fresh-cut industry is a HACCP system. A HACCP system allows managers to assess the inherent risks and identify hazards attributable to a product or a process, and then determine the necessary steps to control the hazards. Monitoring and verification steps, which include recordkeeping, are included in the HACCP system to ensure that potential risks are controlled. We use HACCP as an example of a preventive control program that a firm may choose based on the recommendations in the guidance to estimate the burden of developing, implementing, and reviewing a preventive control program.

FDA estimated the paperwork burden of developing and implementing a HACCP plan based on a plan with two CCPs. The number of CCPs may vary depending on how the processor chooses to identify the CCPs for a particular operation. Developing a HACCP plan is a one-time activity that is estimated to take 100 hours based on a trained HACCP team working on the plan full time. The HACCP team identifies the CCPs and measures needed to control them, and then identifies the approach needed to verify the effectiveness of the controls. During this plan development period, the firm chooses the records to be kept and information and observations to be recorded. This is a one-time process during the first year.

In 2007, we previously estimated that, of the estimated 250 fresh-cut processors, approximately 50 percent of the firms already have HACCP plans in place. We therefore assumed that the remaining fresh-cut processors (125 existing firms plus the 10 new firms), would voluntarily develop a HACCP plan, and estimated that 135 processors would spend 13,500 hours (135 x 100) to develop their individual HACCP plans. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry annually in the next 3 years. We estimate that the 10 new firms will spend 100 hours each to develop their individual HACCP plans, for a total of 1,000 hours (10 x 100). This burden estimate is shown in row 4 of table 1 of this document.

After the HACCP plan is developed, the frequency for recordkeeping for implementing or maintaining daily records is estimated to be 510 records per year. (This is based on a firm choosing to maintain daily records for 2 CCPs for one 8-hour shift per day for each of the estimated 255 operational days per year.) The total time to record observations for the CCPs was estimated to take 4 minutes or 0.067 hours per record. Therefore, the total annual records kept by 145 firms (the 135 firms plus the 10 new businesses expected to enter the industry) is 73,950 (510 x 145), and the total hours required are 4,955 (73,950 records x 0.067 hours per record = 4,954.65, rounded to 4,955). This annual burden is shown in row 5 of table 1 of this document.

After the HACCP plan has been developed and implemented, we recommend that the plan is reviewed regularly to ensure that it is working properly. Fresh-cut processors are estimated to review their HACCP plans four times per year (once per quarter). Assuming that it takes each of the 145

firms 4 hours per review each quarter, the total burden of this activity, for firms that choose to review their plans annually, is 2,320 (145 x 4 x 4) hours per year. This annual burden is shown in row 6 of table 1 of this document.

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19747 Filed 8–10–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ORR Requirements for Refugee Cash Assistance; and Refugee Medical Assistance (45 CFR Part 400).

OMB No.: 0970–0036.

Description: As required by section 412(e) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from Form ORR–6 to determine the effectiveness of the State cash and medical assistance, child welfare, social services, and targeted assistance programs. State-by-State Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) utilization rates derived from Form ORR–6 are calculated for use in formulating program initiatives, priorities, standards, budget requests, and assistance policies. ORR regulations require that State Refugee Resettlement and Wilson-Fish agencies, and local and Tribal governments complete Form ORR–6 in order to participate in the above-mentioned programs.

Respondents: State Refugee Resettlement and Wilson-Fish Agencies, local, and Tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–6	50	3	3.88	582

Estimated Total Annual Burden Hours: 582.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project.

Fax: 202–395–7285.

Email: *OIRA_SUBMISSION@OMB.EOP.GOV.*

Attn: Desk Officer for the Administration for Children and Families.

Dated: August 5, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–19748 Filed 8–10–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0198]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification

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 September 10, 2010.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0120. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

Premarket Notification—(OMB Control Number 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol, Humanitarian Device Exemption (HDE), Petition for Evaluation of Automatic Class III Designation (de novo) or be reclassified