

The burden estimates in table 1 of this document are based on those in the final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute (RTI) in the “Survey of Manufacturing Practices in the Dietary Supplement Industry” cited in that rule.

The estimates in table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehouseurs that reported in the survey that they have not established written standard operating procedures (SOPs) or do not maintain records that were later required by the final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehouseurs. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, “What must the batch production record include?” The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 of this document reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260 (what the batch record must include).

Dated: September 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24105 Filed 9–24–10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0434]

Draft Guidance for Industry: Acidified Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Guidance for Industry: Acidified Foods.” The draft guidance, when finalized, will complement FDA’s regulations regarding acidified foods, including regulations for specific current good manufacturing practice (CGMP), establishment registration, and process filing. The draft guidance is intended to assist commercial food processors in determining whether their food products are subject to these regulations. The draft guidance also is intended to assist processors of acidified foods in ensuring safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures. Under the draft guidance, processors of non-acidified foods (e.g., some acid foods or fermented foods) who are not subject to the acidified food regulations may choose to voluntarily register and file scheduled processes with us using existing forms (Forms FDA 2541 and 2541a). If such processors voluntarily submit this information, we plan to make the results of any FDA evaluation of the information available to our investigators, e.g., during inspections of food facilities and during evaluations of foods offered for import.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments concerning the draft guidance by December 27, 2010. Submit either electronic or written comments concerning the collection of information provisions by December 27, 2010.

ADDRESSES: Submit electronic comments on the draft guidance and the

proposed collection of information provisions to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance entitled “Guidance for Industry: Acidified Foods” to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–436–2669. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance document: Michael Mignogna, Center for Food Safety and Applied Nutrition (HFS–302), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301–436–1565.

With regard to the information collection: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Guidance for Industry: Acidified Foods.” The draft guidance, when finalized, will complement FDA’s regulations regarding acidified foods, including regulations for specific CGMP, establishment registration, and process filing. The draft guidance is intended to assist commercial food processors in determining whether their food products are subject to these regulations. Under the draft guidance, processors of acid foods and fermented foods who conclude that such foods they produce are not also acidified foods¹ may voluntarily register and file scheduled processes with us using existing forms (Forms FDA 2541 and 2541a) for acidified foods. Processors of

¹ Fermented foods, such as some kinds of sauerkraut, cucumber pickles, and green olives, are low-acid foods subjected to the action of acid-producing microorganisms to reduce the pH of the food. Not all fermented foods meet the definition of “acidified foods” in 21 CFR 114.3(b). However, some fermented foods that contain acid are also acidified foods. We also note that fermented dairy products, such as yogurt, belong to a separate category that is not relevant to the fermented foods that are discussed in this guidance.

acid foods and fermented foods, which foods are not also acidified foods, would not be subject to the acidified food regulations. When processors of such acid foods or fermented foods voluntarily register and file scheduled processes with us using existing forms, we plan to make the results of any FDA evaluation of such information available to our investigators, e.g., during inspections of food facilities and during evaluations of foods offered for import, to facilitate investigators' decisions about the regulatory status of those food products. The draft guidance recommends that such processors, who voluntarily file scheduled processes with us, file a single scheduled process for each product, rather than filing a separate form for each container size, as required for processors of acidified foods. The draft guidance also is intended to assist processors of acidified foods in ensuring safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures. FDA is issuing this draft guidance as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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.

Title: Recommendations for Establishment-Specific Written Quality Control Plans and Recordkeeping for Acidified Foods, and Voluntary Registration and Process Filing.

Description of respondents: The likely respondents to this proposed collection of information are processors of acidified foods as well as processors of foods that may not be acidified foods who voluntarily choose to provide us with information about these foods.

Description: The draft guidance is intended to assist processors of acidified foods in ensuring safe manufacturing, processing, and packing processes and in employing appropriate quality control procedures. Further, this guidance notes that processors who are not certain as to whether specific food products, including foods that may be acid or fermented foods, are acidified foods subject to registration and process filing requirements may provide us with information about these products by voluntarily submitting Forms FDA 2541 and 2541a. This guidance also recommends that firms prepare a written plan to investigate product lots for signs of spoilage and document any investigation and corrective actions relevant to spoilage.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in § 108.25 (21 CFR 108.25) and part 114 (21 CFR part 114) have been approved under OMB control no. 0910–0037.

Under the draft guidance, when processors voluntarily submit Forms FDA 2541 and 2541a for foods that they conclude are not acidified foods, we intend to continue to evaluate the process information to determine whether it is consistent with a processor's conclusion that a food is not an acidified food. The burden approved under OMB control no. 0910–0037 does not include the burden associated with voluntary reporting.

The burden approved under OMB control no. 0910–0037 also does not include the burden associated with the recommendations in the draft guidance

to prepare a written plan (the establishment-specific written plan) that includes quality control procedures with respect to spoilage and to document spoilage events if they occur. We estimate the recordkeeping burden of the draft guidance by assuming that those in the industry that process acidified foods and that do not currently follow the recommendations put forth in the draft guidance will find it of value to do so. The conservative assumptions and estimates made in this analysis regarding the recordkeeping burden are intended to provide the upper bound estimates of anticipated impact of the guidance on the acidified food industry and others that choose to file voluntary submissions with FDA. These burdens would be realized if every operation, plant, or processor of acidified foods that does not already follow the recommendations of the draft guidance would choose to do so.

We estimate the proposed collection of information consists of one-time and recurring recordkeeping burdens, summarized in table 1 of this document.

We estimate the reporting burden of the draft guidance by assuming that processors who conclude that their specific food products are acid foods or fermented foods, rather than acidified foods subject to registration and process filing requirements, will find it of value to provide us with information about their products by voluntarily submitting Forms FDA 2541 and 2541a. The conservative assumptions and estimates made in this analysis regarding the reporting burden are intended to provide the upper bound estimates of anticipated impact of the guidance on such processors. These burdens would be realized if every operation, plant, or processor that concludes that specific food products are acid or fermented foods that are not also acidified foods, would choose to submit Forms FDA 2541 and 2541a. We estimate that the proposed collection of information consists of one-time and recurring reporting burdens, summarized in table 2 of this document.

Current Information Available to FDA

The existing reporting requirements in § 108.25 provide us with information about the acidified foods industry, including the total number of establishment registrations, the annual number of establishment registrations, and the annual number of processes filed. As of February 4, 2010, there are a total of 4,872 establishments registered with FDA in accordance with § 108.25 as commercial processors of acidified foods.

The available data for the past 6 years (2004 through 2009)² indicate that, on average, there are 6,754 process filings submitted by an average of 892 acidified foods establishments each year. In addition, since 2004, when we began implementing an electronic filing system, approximately 750 establishments that registered using Form FDA 2541 submitted process filings to us for food products that we determined were not covered by either part 113 (21 CFR part 113) or part 114. The available information includes the number of establishments that submitted such filings, but not the number of filings.

We also have data on estimated reporting burdens, available to us from our most recent analysis of the reporting burden under parts 113 and 114 (OMB control no. 0910-0037; 73 FR 11649 at 11650, March 4, 2008). In that analysis, we estimated that there are 8,950 establishments that keep records on an annual basis as processors of acidified foods or low-acid canned foods (LACF), that 515 establishments submit a registration form (Form FDA 2541) on an annual basis, for either acidified foods or LACF; that it takes 0.17 hours to complete Form FDA 2541; that 1,489 establishments each submit 8.62 process filings (Form FDA 2541a) on an annual basis; and that it takes 0.33 hours to complete Form FDA 2541a. We use this information to estimate the reporting burden associated with the draft guidance.

In addition to establishment registration and process filing under § 108.25, acidified food establishments also must promptly report to us any instance of spoilage when the nature of the spoilage is such that it has potential health-endangering significance and any lot of such food has in whole or in part entered distribution in commerce (§ 108.25(d)). In the period from 2004 to January 2010, we received 1 report of spoilage of a commercially distributed acidified food. Therefore, for this

analysis, we assume that such spoilage events are rare.

Recordkeeping Burden

Establishment-Specific Written Plan Including Quality Control Procedures for Acidified Foods (One-Time Burden): Currently, acidified foods establishments must employ appropriate quality control procedures to ensure that finished foods do not present a health hazard (§ 114.80(a)). To assist manufacturers in employing appropriate quality control procedures under § 114.80(a), the draft guidance recommends that each acidified food establishment prepare a written plan (the establishment-specific written plan) that includes quality control procedures with respect to spoilage, regardless of whether the spoilage has potential health-endangering significance. Currently existing models (e.g., Ref. 1) suitable for use in developing such a written plan are readily available to acidified foods establishments.

Because we rarely receive reports under § 108.25(d) regarding spoilage of commercially distributed acidified foods with potential health-endangering significance, for this analysis we assume that the quality control procedures of all acidified foods establishments currently address spoilage. Because the potential health consequences of spoilage may not be apparent in the initial stages of an investigation of spoilage, we assume that these establishments address spoilage regardless of the potential for health consequences. We also assume that the quality control procedures of 80 percent of registered establishments address spoilage through an establishment-specific written plan such as the one recommended in the draft guidance. We further assume that the quality control procedures of the remaining 20 percent of registered establishments (i.e., $4,872 \times 0.20 = 974.4$, rounded to 974 establishments) address spoilage by relying on a generally available document (e.g., Ref. 1), the establishment's unwritten

procedures, or a combination of both. Based on our experience with quality control procedures, we estimate it would take 8 hours for an acidified foods establishment to prepare an establishment-specific written plan. If all of the 974 registered establishments that do not currently have an establishment-specific written plan develop such a plan, the associated recordkeeping burden would be 7,792 hours (974 establishments \times 8 hours/establishment). This would be a one-time recordkeeping burden. Table 1 of this document includes the estimated one-time recordkeeping burden associated with preparation of establishment-specific written plans.

Documentation of Spoilage for Acidified Foods (Recurring Burden): The draft guidance recommends that an acidified food establishment document all investigations and corrective actions relevant to spoilage. We assume that an acidified food establishment that currently has an establishment-specific written plan in place to address spoilage also currently documents investigations and corrective actions relevant to spoilage. We assume that spoilage problems are relatively rare and, therefore, estimate that one spoilage event per establishment occurs every 5 years. Accordingly, we estimate 195 spoilage events requiring recordkeeping will occur (974 establishments that do not currently have an establishment-specific written plan \times 0.2 events/establishment = 194.8 events, rounded to 195). Assuming that establishments follow procedures such as those in Ref. 1, and based on our experience with investigations and corrective actions, we estimate it would take 2 hours to document a spoilage event. Thus, we estimate a recurring recordkeeping burden of 390 hours (195 events \times 2 hours/event = 390 hours). Table 1 of this document includes the estimated recurring recordkeeping burden associated with documenting investigations of spoilage events.

TABLE 1.—ESTIMATED ONE-TIME AND RECURRING RECORDKEEPING BURDEN¹

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Quality control plan to address spoilage ²	974	1	974	8.00	7,792
Spoilage event documentation	195	1	195	2.00	390
Total one-time burden					7,792

² We began implementing an electronic filing system in 2004 and used information available in that system for this analysis.

TABLE 1.—ESTIMATED ONE-TIME AND RECURRING RECORDKEEPING BURDEN¹—Continued

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Total recurring burden					390

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

² One-time recordkeeping burden.

Reporting Burden

Voluntary Registration (Form FDA 2541) (One-Time and Recurring Burdens): Currently, we place information documenting whether acidified food establishments have made appropriate submissions on Forms FDA 2541 and 2541a in an acidified food database that is readily available to our investigators who inspect food facilities or evaluate foods offered for import. This information facilitates decisions by our investigators about the regulatory status of specific food products.

In our experience, establishments are cautious about decisions they make about the regulatory status of their products, and many establishments that process non-acidified fermented foods and/or acid foods have contacted us with information about their facilities and the products they make. For example, our records show that, since 2004, we have informed approximately 750 different registered establishments that submitted electronic process filings that a food product that was the subject of a process filing was not covered by either part 113 (as a low-acid food) or part 114 (as an acidified food). In the past, we did not add information about these products to the acidified foods databases that are available to our investigators.

The draft guidance clarifies that establishments that conclude that the foods they process are acid foods or fermented foods that are not also acidified foods, may voluntarily register and file scheduled processes with us using Forms FDA 2541 and 2541a. As we do currently, if we receive information from such establishments, we would evaluate the submitted information to determine whether it is consistent with the establishment's conclusion that a product is not an acidified food. We plan to make the results of these evaluations available to our investigators, for example, during inspections of food facilities and during evaluations of foods offered for import. If we conclude that the submitted information is not consistent with the processor's conclusion that its products are not acidified foods, we may request additional information to assist us in evaluating the processor's conclusion

about its products or take other action as appropriate. From our past experience, we believe that many processors of foods that may be acid foods or fermented foods that are not also acidified foods would choose to submit information to us on Forms FDA 2541 and 2541a because doing so would facilitate decisions by our investigators about the regulatory status of specific food products.

We estimate that there are 3,000 establishments that process products that they would conclude are acid foods or fermented foods that are not also acidified foods—4 times the approximate number of registered establishments (750) that have submitted process filings to FDA for food products we determined were not covered by either part 113 or part 114. We assume that all 3,000 establishments are not already registered as processors of acidified foods or LACF. Because 750 of these establishments have already registered voluntarily using Form FDA 2541, we estimate that the number of establishments that may register for the first time under the draft guidance is 2,250 establishments (3,000 - 750 = 2,250), resulting in a one-time reporting burden of 383 hours (2,250 establishments x 0.17 hours/establishment = 382.5 hours, rounded to 383 hours). Table 2 of this document includes the estimated one-time reporting burden for establishments that conclude that their foods are acid foods or fermented foods that are not also acidified foods, and voluntarily register their facilities in the first year after the draft guidance is issued.

After this initial registration, we also estimate that, on average, a number of establishments equal to 6 percent of the 3,000 total estimated establishments that will voluntarily register in the first year (i.e., 0.06 x 3,000 establishments = 180 establishments) will voluntarily register using Form FDA 2541 each year, resulting in an annual reporting burden of 31 hours (180 establishments x 0.17 hours/establishment = 30.6 hours, rounded to 31 hours). Proportionally, this would be comparable to the current percentage of acidified foods and LACF establishments that, on average, register using Form FDA 2541 each year (515 establishments that register on an

annual basis/8,950 establishments that keep records on an annual basis x 100 = 5.75 percent rounded to 6 percent). Table 2 of this document includes the estimated recurring annual reporting burden for establishments that process foods that they conclude are acid foods or fermented foods that are not also acidified foods, and that would voluntarily register their facilities.

Voluntary Process Filing (Form FDA 2541a) (One-Time and Recurring Burdens): As discussed, we do not have information about the number of process filings voluntarily submitted by firms that registered their establishments but whose food products we determined were not covered by either part 113 or part 114. However, we do have information that, on average, over the 6-year period from 2004 through 2009, there was a total of 6,754 annual process filings submitted by an average of 892 acidified foods establishments each year, and that there were 4,872 registered acidified foods establishments; from this information we calculate that, on average, 18 percent of registered acidified foods establishments submit process filings each year (892 establishments/4,872 establishments x 100 = 18.3 percent, rounded to 18 percent). To be conservative, we also estimate that, on average, acidified foods establishments submitted process filings for 3 container sizes per product and that the total number of products reported by acidified foods establishments each year during that period was thus 2,251 products (6,754 process filings/3 container sizes/product = 2,251.33 products, rounded to 2,251 products). For the purpose of this analysis, we estimate that, on average, 18 percent of establishments that process foods that they conclude are acid foods or fermented foods that are not also acidified foods in a given year will submit process filings; i.e., 540 establishments (0.18 x 3,000 establishments = 540 establishments). To be conservative, we also estimate that, on average, the 540 establishments that would submit process filings in a given year will submit process filings for twice as many products as would be submitted by acidified foods establishments; per the

recommendations in the draft guidance, these establishments could submit a single process form that covers all container sizes of a product. Thus, the estimated number of annual voluntary process filings is 2,725 process filings (2,251 products/892 establishments x 540 establishments x 2 = 2,725.4 process filings, rounded to 2,725). On average, we calculate that the annual frequency of reporting would be 5 process filings (2,725 process filings/540 establishments = 5.04, rounded to 5). For the purpose of this analysis, we use the rounded number of process filings (i.e., 5) and, thus, calculate that the estimated recurring reporting burden for

submission of Form 2541a is 2,700 process filings rather than 2,725 process filings (540 establishments x 5 process filings per establishment = 2,700 process filings), resulting in an annual reporting burden of 891 hours (2,700 process filings x 0.33 hours/process filing = 891 hours). Table 2 of this document includes the estimated one-time and recurring reporting burden for establishments that voluntarily submit process filings for foods that they conclude are acid foods or fermented foods that are not also acidified foods.

We also estimate that all 3,000 establishments that process foods that they conclude are acid foods or fermented foods that are not also

acidified foods and voluntarily register their establishments will submit a total of 30,000 process filings in the first year—i.e., twice as many process filings as would be submitted, on average, by any given establishment on an annual basis (2 x 5 process filings/establishment on an annual basis x 3,000 establishments = 30,000 process filings), resulting in a one-time reporting burden of 9,900 hours (30,000 process filings x 0.33 hours/establishment = 9,900 hours). Table 2 of this document includes the estimated one-time reporting burden for establishments that voluntarily submit process filings for fermented foods and/or acid foods.

TABLE 2.—ESTIMATED ONE-TIME AND RECURRING REPORTING BURDEN¹

Activity	No. of Reporters	Annual Frequency per Reporter	Total Annual Records	Hours per Record	Total Hours
Registration (Form FDA 2541) ²	2,250	1	2,250	0.17	383
Registration (Form FDA 2541)	180	1	180	0.17	31
Process filing (Form FDA 2541a) ²	3,000	10	30,000	0.33	9,900
Process filing (Form FDA 2541a)	540	5	2,700	0.33	891
Total one-time burden					10,283
Total recurring burden					922

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

² One-time reporting burden.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov> or at <http://www.fda.gov/FoodGuidances>.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent

changes to Web site after this document publishes in the **Federal Register**.)

1. Codex Alimentarius Commission, Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods CAC/RCP 23–1979, Rev. 2 (1993), Available at http://www.codexalimentarius.net/download/standards/24/CXP_023e.pdf, Accessed and printed on June 17, 2008.

Dated: September 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.
[FR Doc. 2010–24089 Filed 9–24–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1820–NC]

Medicare and Medicaid Programs; Announcement of an Application for a Hospital Requesting Waiver for Organ Procurement Service Area

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: A hospital has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated Organ Procurement Organization (OPO). The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.