

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

| Data collection task | Instrument/form name | Number of respondents | Number responses/ respondent | Average burden/ response (in hours) | Total response burden (in hours) |
|---|--------------------------------|-----------------------|------------------------------|-------------------------------------|----------------------------------|
| In person focus groups (public health professionals). | Screener | 140 | 1 | 10/60 | 23.3 |
| | Focus Group | 70 | 1 | 1.5 | 105 |
| | Confidentiality Agreement | 70 | 1 | 5/60 | 6 |
| Remote focus groups (consumers with limited health literacy and/or Spanish speakers). | Screener | 168 | 1 | 10/60 | 28 |
| | Focus Group | 42 | 1 | 1.5 | 63 |
| | Confidentiality Agreement | 42 | 1 | 5/60 | 3.5 |
| Remote focus groups (health intermediaries). | Screener | 126 | 1 | 10/60 | 21 |
| | Focus Group | 42 | 1 | 1.5 | 63 |
| | Confidentiality Agreement | 42 | 1 | 5/60 | 3.5 |
| Remote focus groups (public health professionals). | Screener | 84 | 1 | 10/60 | 14 |
| | Focus Group | 42 | 1 | 1.5 | 63 |
| | Confidentiality Agreement | 42 | 1 | 5/60 | 3.5 |
| In person usability and prototype testing of materials (print and Web). | Screener | 160 | 1 | 10/60 | 27 |
| | Usability Test | 40 | 1 | 1.5 | 60 |
| | Confidentiality Agreement | 40 | 1 | 5/60 | 3.3 |
| Remote usability, prototype and concept testing. | Screener | 200 | 1 | 10/60 | 33.3 |
| | Web-test | 50 | 1 | 1 | 50 |
| | Confidentiality Agreement | 50 | 1 | 5/60 | 4.2 |
| In person card sorting | Screener | 120 | 1 | 10/60 | 20 |
| | Card Sort | 30 | 1 | 1.5 | 45 |
| | Confidentiality Agreement | 30 | 1 | 5/60 | 2.5 |
| Web-based card sorting | Screener | 400 | 1 | 10/60 | 67 |
| | Card Sort | 100 | 1 | .5 | 50 |
| | Confidentiality Agreement | 100 | 1 | 5/60 | 8.3 |
| Web-based message testing | Screener | 0 | 0 | 0 | 0 |
| | Web-test | 115 | 1 | 1 | 115 |
| | Confidentiality Agreement | 115 | 1 | 5/60 | 9.6 |
| TOTAL | | | | | 1329.1 |

Keith A. Tucker,
 Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.
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OMB No.: 0970-0033.
Description: The Annual Survey of Refugees collects information on the social and economic circumstances of a random sample of refugees, Amerasians, and entrants who arrived in the United States in the five years prior to the date of the survey. The survey focuses on the refugees training, labor force participation, and welfare utilization rates. Dates are segmented by region of origin, State of resettlement, and number of months since arrival. From the responses, the Office of Refugee Resettlement reports on the economic adjustment of refugees to the American economy. These data are used by

Congress in its annual deliberations for refugee admissions and funding and by program managers in formulating policies for the future direction of the Refugee Resettlement Program.

Respondents: Refugees, entrants, Amerasians, and Havana parolees.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Survey of Refugees (Form ORR-9).

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| ORR-9 Annual Survey of Refugees | 2,000 | 1 | 0.63 | 1,253.20 |
| Request for Participation Letter | 2,000 | 1 | 0.04 | 80 |

Estimated Total Annual Burden
Hours: 1,333.20.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email 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, Email: OIRA_SUBMISSION@OMB.EOP.GOV.

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

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0306]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

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 information collection for administrative detention and banned medical devices.

DATES: Submit either electronic or written comments on the collection of information by June 11, 2012.

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:

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: 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.

Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), on administrative detention, includes among other things, certain reporting requirements and recordkeeping requirements. Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the FD&C Act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. Section 895.21 (21 CFR 895.21), on banned devices, contains certain reporting requirements. Section 895.21(d) describes the procedures for banning a device when the Commissioner of Food and Drugs (the Commissioner) decides to initiate such a proceeding. Under 21 CFR 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of three firms whose devices had been detained.

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