

register. Therefore, FDA estimates that zero vending machine operators will register with FDA under section 4205 of the Affordable Care Act.

According to The NPD Group's Spring 2010 ReCount report, there were 579,416 sole purpose eating and drinking establishments in the United States in the winter of 2010 (Ref. 2). Of these, 40 percent will be explicitly subject to FDA rulemaking for the Affordable Care Act because they are part of chains with 20 or more outlets (Ref. 2). Of the remaining 350,000 outlets, only those that would be subject to local or State rules concerning menu labeling would have any incentive to register. Approximately 7.5 percent of restaurant outlets are in States or localities with currently operational menu labeling regulation, principally New York City, Oregon, Philadelphia, and some New York State counties (Ref. 3). NPD's Spring 2010 ReCount report shows a total of 20,000 outlets are part of chains with between 10 and 19 establishments. If outlets are evenly distributed geographically, then 1,500 outlets and 103 restaurant firms may have an incentive to register with FDA. The hourly burden for restaurant chains is 206 hours (=100 chains × 1 responses/chain/year × 2 hours/response).

From the U.S. Census County Business Patterns data, FDA estimates that there are approximately 62,000 grocery stores in 2010. Of these, approximately 6,500 are "independents" which means that they are part of chains with fewer than 11 outlets (Ref. 4), and 35,000 are known to belong to chains with more than 20 outlets (Ref. 5). We round the remaining 20,523 outlets up to 21,000 to account for those outlets in chains with 10 or 11 establishments. County Business Patterns show that 11.5 percent of all grocery stores are in jurisdictions that have relevant menu labeling regulations. Taking 11.5 percent of 21,000 yields approximately 2,400 stores run by 167 firms. The hourly burden for grocery chains is 334 hours (= 167 chains × 1 responses/chain/year × 2 hours/response).

According to Stagnito Media, there are 144,000 convenience store outlets in the United States (Ref. 6). Of these, 64,000 are defined as very small "mom and pop" locations. Approximately 60,000 outlets are controlled by 1 of top 100 chains, each having at least 65 outlets (Ref. 7). Of the remaining 20,000, FDA estimates that half fall in the 10 to 19 outlet range. From County Business Patterns (Ref. 3), 1.6 percent of all convenience store outlets are in a jurisdiction with a local or State menu labeling regulation that does not explicitly exempt convenience stores.

FDA estimates that approximately 160 convenience store outlets from 11 firms may have an incentive to register under this notice. The hourly burden for convenience store chains is 22 hours (=11 chains × 1 responses/chain/year × 2 hours/response).

Additional covered establishments, such as those operating in lodging, corporate, entertainment, and educational settings are often provided by very large firms with many hundreds or thousands of outlets, and will thus be explicitly covered by section 4205 of the Affordable Care Act rather than by the registration provisions. FDA estimates that an additional 81 firms, controlling approximately 1,200 outlets may have an incentive to register. The hourly burden for these additional chains is 162 hours (= 81 chains × 1 responses/chain/year × 2 hours/response).

If all of these restaurant and similar retail food establishment chains choose to register with FDA, then FDA estimates the number of firms registering in the first year would be approximately 362 firms. At 2 hours per registration, the total initial hourly burden will then be 724 hours (= 362 firms × 2 hours/firm).

FDA estimates that the rate of growth for chains entering the 10 to 19 outlet segment will match the rate of growth out of this segment, so that the number of registrants will remain constant. County Business Patterns data shows an average growth rate in the number of establishments to be 2 percent per year over the 8 years from 1999 to 2007 for restaurants (Ref. 3). If the restaurant growth rate for outlets of approximately 2 percent per year applies to these chains, then new registrants will amount to approximately 7 per year, with the remaining 355 registrants only renewing their registration. The yearly burden for registration is estimated to be 1 hour per new registrant. Thus, the total hour burden will be 7 hours (7 firms × 1 hour/firm). The yearly burden for renewing registration is estimated to be 0.25 hour per continuing registrant. Thus, the total hour burden will be 89 hours (355 firms × 0.25 hour/firm = 88.75, rounded to 89). This yields a recurring hourly burden of 96 hours per year (7 hours + 89 hours).

II. References

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

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

1. Food and Drug Administration. 2003. "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 68 FR 5378, February 3, 2003.
2. The NPD Group, "Chains System Size Trend Report for U.S. FDA," *ReCount*, Spring 2010.
3. U.S. Census Bureau, 2007, County Business Patterns, <http://www.census.gov/econ/cbp/index.html>, 2007, version date September 22, 2009.
4. Moran, M., J. McTaggart, and D. Chanil, "Looking Up, Cautiously," *Progressive Grocer* 89(3): 20–52, 2010.
5. Food Marketing Institute, Top U.S. Supermarket & Grocery Chains (by 2007 grocery sales), <http://www.fmi.org>, 2008.
6. Stagnito Media, "Directory of Convenience Stores: FAQ," <http://www.conveniencestores.com/faq.html>, accessed June 1, 2010.
7. Longo, D. "Convenience Store News: Hot Top 100" *Convenience Store News*, 45(10), pp. 27–32, August 10, 2009.

Dated: January 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2001-D-0254; formerly Docket No. 2001D-0037]

Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" dated January 2011. The draft guidance document provides blood establishments with recommendations for pre-storage leukocyte reduction of Whole Blood and blood components intended for transfusion, including recommendations for validation and quality control monitoring of the leukocyte reduction process. This second draft guidance document incorporates revisions after reviewing comments on the January 2001 draft. This draft guidance replaces the draft guidance of the same title dated January 2001. This draft guidance, when

finalized, will supersede the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

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 on the draft guidance by May 2, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised, second draft document entitled "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion" dated January 2011. The draft guidance document provides blood establishments with recommendations for pre-storage leukocyte reduction of Whole Blood and blood components intended for transfusion, including recommendations for validation and quality control monitoring of the leukocyte reduction process. The draft guidance provides information to assist licensed blood establishments for submitting biologics license application supplements to include leukocytes reduced components. This second draft guidance document incorporates revisions after reviewing comments on the January 2001 draft, and in consideration of

additional public discussions held at the June and December 2001 meetings of the Blood Products Advisory Committee and the July 2005 public workshop entitled "Update on Leukocyte Reduction of Blood and Blood Components." This draft guidance replaces the draft guidance of the same title dated January 2001 (January 31, 2001, 66 FR 8410). The draft guidance, when finalized, will supersede the FDA memorandum issued on May 29, 1996, entitled "Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products."

The draft guidance is being issued 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 607 have been approved under OMB control number 0910-0052; the collections of information in 21 CFR 606.100(b), 606.100(c), and 606.121 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 211.192 and 211.198 have been approved under OMB control number 0910-0139; and the collections of information in 21 CFR 601.12 and 610.60 have been approved under OMB control number 0910-0338.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: January 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0281]

Guidance for Industry and Food and Drug Administration Staff: "Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act"; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled "Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act." This guidance provides written guidance to industry and FDA staff on certain provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Submit either electronic or written comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your requests or include a fax number to which the guidance document may be sent. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.