Estimated labor costs: $21,570.

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff further assumes that office support file clerks will handle the Rule's record retention requirements at an hourly rate of $14.38.[13] Based upon the above estimates and assumptions, the total annual labor cost to retain and file documents, for the FTC's allotted burden, is $21,570 (1,500 hours × $14.38 per hour).

Absent information to the contrary, staff anticipates that existing storage media and equipment that covered persons use in the ordinary course of business will satisfactorily accommodate incremental recordkeeping under the Rule. Accordingly, staff does not anticipate that the Rule will require any new capital or other non-labor expenditures.

Request for Comments

You can file a comment online or on paper. Write ''Regulation N: FTC File No. P134811; K05'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential,'' as discussed in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/regulationnpra* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Regulation N: FTC File No. P134811; K05'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610, (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610, (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 31, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

David C. Shonka,

Acting General Counsel.

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entities can be indirectly covered by state recordkeeping requirements for mortgage advertisements and/or retain ads to demonstrate compliance with state law, as discussed above. *See supra* note 6. The FTC notes that the CFPB's recent information collection filing with OMB for Regulation N also reflects the view that, in large part, most entities either retain records in the ordinary course of business or to demonstrate compliance with other laws. *See generally* Bureau of Consumer Financial Protection, Agency Information Collection Activities: Submission for OMB Review; Comment Review, 80 FR 45645 (July 31, 2015), *available at https://www.gpo.gov/fdsys/pkg/FR-2015-07-31/pdf/2015-18809.pdf.*

[13] This estimate is based on mean hourly wages for office support file clerks provided by the Bureau of Labor Statistics. *See* U.S. Bureau of Labor Statistics, Occupational Employment and Wages—May 2015, table 1 (''National employment and wage data from the Occupational Employment Statistics survey by occupation''), released Mar. 30, 2016, *available at http://www.bls.gov/news.release/pdf/ocwage.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From QAISys, Inc.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from QAISys, Inc. of its status as a PSO, and has delisted the PSO accordingly. QAISys, Inc. submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on August 10, 2016.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ,

5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the QAISys, Inc., PSO number P0161, to voluntarily relinquish its status as a PSO. Accordingly, QAISys, Inc. was delisted effective at 12:00 Midnight ET (2400) on August 10, 2016. AHRQ notes that that QAISys, Inc. submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on July 28, 2016. In addition, QAISys, Inc., P0046, was previously listed as a PSO in 2009; AHRQ accepted its request for voluntary relinquishment in 2013.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov.*

Sharon B. Arnold,

Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2495]

Submission of Warning Plans for Cigars; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submission of Warning Plans for Cigars.'' The draft guidance, when finalized, will help those involved in the manufacture, distribution, and sale of cigars in the United States understand the new cigar warning plan requirements under FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance reiterates the required health warning statements and the requirements for random display and distribution that should be provided in cigar warning plans, and, when finalized, will help persons determine who should submit a warning plan, when a plan must be submitted, and what information should be included when submitting a plan.

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 September 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2495 for ''Submission of Warning Plans for Cigars.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in