geographic market in which to analyze the competitive effects of the acquisition is the United States and Canada. Hollander and Actual Systems are closest competitors in this market and are two of only three competitively meaningful YMS providers.

III. Effects of the Acquisition

The acquisition is likely to result in significant anticompetitive harm in the highly-concentrated YMS market. Solera and Actual Systems were two of only three significant competitors in this market. The acquisition has eliminated actual, direct, and substantial competition between Solera and Actual Systems, and likely will result in higher prices and reduced innovation for YMS.

IV. Entry

Entry or repositioning is not likely to avert the anticompetitive impact of Solera's acquisition of Actual Systems. The time and cost required to develop a YMS are substantial, and far outweigh the potential profit incentives for either new entrants or firms operating in adjacent markets. In addition, it would be difficult for a new entrant to obtain a license to the Hollander Interchange, an auto parts database required to compete in the YMS market.

V. The Proposed Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the transaction by requiring Solera to divest assets related to Actual Systems' United States and Canadian business to ASA Holdings. This divestiture preserves competition that was eliminated as a result of the acquisition.

ASA Holdings is comprised of individuals with extensive experience with Actual Systems and the YMS market. The main principal of ASA Holdings is Peter Riddle. Mr. Riddle founded ASUK in 1985, developed the base YMS software program that would become Actual Systems' YMS, and formed Actual Systems in the United States. The other members of ASA Holdings are Emilio Fontana and Peter Bishop. Mr. Fontana was involved with Actual Systems since the mid-1990s, including serving as a member of its Board of Directors. Mr. Bishop worked for Actual Systems for over 10 years, including serving as its General Manager and Director from 2004 until its acquisition by Solera. The terms required by the proposed Consent Agreement will enable ASA Holdings to effectively replace the competition in the YMS market lost as a result of the acquisition.

The proposed Consent Agreement also contains several provisions designed to ensure that the divestiture is successful. For instance, Solera must provide ASA Holdings with a license to the Hollander Interchange lasting the length of the proposed Consent Agreement.

If the Commission determines that ASA Holdings is not an acceptable acquirer of the assets to be divested, or that the manner of the divestiture is not acceptable, Solera must rescind the divestiture and divest the assets within 120 days of the date the Order becomes final to another Commission-approved acquirer. If Solera fails to divest the assets within the 120 days, the Commission may appoint a trustee to divest the relevant assets.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–18070 Filed 7–26–13; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0865]

The Patient Preference Initiative: Incorporating Patient Preference Information Into the Medical Device Regulatory Processes: Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes.'' The purpose of the workshop is to discuss ways to incorporate patient preferences on the benefit-risk tradeoffs of medical devices into the full spectrum of the Center for Devices and Radiological Health (CDRH) regulatory decision making. It also aims to advance the science of measuring treatment preferences of patients, caregivers, and health care providers. The information learned from this workshop and public comments will benefit regulators, industry, providers, patients, and device innovators.

Date and Time: The public workshop will be held on September 18 and 19, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Section A of the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*

Contact Person: Nada Hanafi, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 3623, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5427, email: *Nada.Hanafi@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 11, 2013, 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the workshop will be available beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan (email: *susan.monahan@fda.hhs.gov* or 301–796–5661) no later than September 4, 2013.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan (*susan.monahan@fda.hhs.gov,* 301–796–5661) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 11, 2013, 4 p.m.

Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 12, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on incorporating patient preferences into medical device regulatory processes. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of measuring patient preference. FDA invites stakeholders to submit their ideas before, during, or after the workshop. The deadline for submitting comments related to this public workshop is October 18, 2013. FDA is also soliciting comments and information for inclusion in the workshop materials. To ensure adequate time for review and incorporation prior to the workshop, FDA encourages stakeholders to submit preliminary information by August 19, 2013.

This public workshop also includes an oral public comment session. FDA intends to allow a 45-minute session for interested stakeholders to raise questions and topics for consideration by the Agency.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is committed to giving patients in the United States access to high-quality, safe, and effective medical devices of public health importance first in the world. A key step toward this goal is to improve the predictability, consistency, and transparency of the premarket review process. In 2012, CDRH published the guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications'' (77 FR 18828; March 28, 2012). This guidance document outlines the principal factors FDA considers when making benefit-risk determinations during the premarket review process for certain medical devices, including data on patient perspectives on meaningful benefits and acceptable risks.

While the benefit-risk guidance outlines a strategy for including patient preference data in the premarket review process, it does not outline which methods, tools, and approaches could be used to collect this information or provide guidance on how to establish and evaluate the validity of evidence necessary for regulatory consideration. Moreover, it is necessary to determine how patient preference data may be used in a broader context of the total product life cycle (TPLC) of medical devices. In addition to the benefit-risk determination, patient preference measurements may also play an important role in device innovation and postmarket analysis. For example, patient dissatisfaction with the side effects of a currently marketed device may suggest the need for postmarket studies, regulatory actions, or may identify an opportunity to develop novel device design features.

CDRH has established the Patient Preference Initiative to provide the information, guidance, and framework necessary to incorporate patient preferences on the benefit-risk tradeoffs of medical devices into the full spectrum of CDRH regulatory processes and to inform medical device innovation by the larger medical device community. In the process, the initiative aims to advance the science of measuring medical device preferences of patients, caregivers, and providers. Once the Patient Preference Initiative helps to define or refine the methods to measure patient preference, CDRH seeks to incorporate patient views into the TPLC of medical devices.

Patients have unique perspectives about the value of the probable benefits and the impact of potential risks of medical devices. Scientists, clinicians, device developers, and regulators play critical roles in understanding the operation of medical devices and the associated benefits and risks. But only patients live with their medical conditions and need to make the choices required for their care. In order to properly take these views into account, investigators must have reliable and accurate methods, tools, and approaches.

Definition of Patient Preference: A composite measurement of patient perceptions or expectations of potential benefits and risks of a purported medical device, measured across the full spectrum of patients who may be exposed to the device. The spectrum should include the full variety of disease presentation, the exposure to the devices, and the demographics of the target or affected patient populations.

II. Topics for Discussion at the Public Workshop

FDA is holding this public workshop to discuss incorporating patient preference information into pre- and postmarket regulatory processes. FDA intends to engage and solicit information from stakeholders on (1) approaches (methods, tools and validation) for capturing, collecting, and validating patient preference information; and (2) the incorporation of patient preference information into regulatory review processes.

In addressing these issues, FDA encourages stakeholders to consider and comment on these questions:

1. How to identify patients and their preferences

- What type of information can/should patients provide?
- What types of information do patients use to formulate decisions about their treatment options?
- Where can patient preference information be found?

2. What approaches should be used to collect patient preference information?

- What methods and tools can be used?
- What are the relative strengths and limitations of these methods and tools?
- Who should collect patient preference information?

3. How to validate patient preference data and information

- What methods and tools can be used?
- Who should validate patient preference information?

4. How to incorporate patient preference information in the regulatory process

- How can FDA use patient preference data within the Total Product Life Cycle regulatory paradigm?
- In what ways should it not be used?
- What additional safeguards should FDA consider when including patient preference information into its regulatory decision making?

Dated: July 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18080 Filed 7–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Advanced Education Nursing Traineeship (AENT) Program application.

OMB No. 0915–XXXX—New.

Abstract: The Health Resources and Services Administration (HRSA) provides advanced education nursing training grants to educational institutions to increase the numbers of advanced education nurses through the AENT Program. The AENT Program is governed by Title VIII, Section 811(a)(2) of the Public Health Service Act, (42 U.S.C. 296j(a)(2)), as amended by Section 5308 of the Patient Protection and Affordable Care Act of 2010, Public Law 111–148. This new request includes the Project Abstract, Program Narrative, Attachments and Tables. The proposed AENT Tables will include information on program participants such as the projected number of enrollees/trainees receiving traineeship support; projected number of graduates receiving traineeship support for the previous fiscal year; the types of programs they are enrolling into and/or from which enrollees/trainees are graduating; and the distribution of primary care nurse practitioners and nurse midwives who plan to practice in rural, underserved, or public health practice settings.

Need and Proposed Use of the Information: The Project Abstract is often distributed to provide information to the public and Congress. HRSA will use this information in determining the amount of traineeship support to be awarded per student per institution and to succinctly capture data for the number of projected students for determining eligibility for Special Consideration and Statutory Funding Preference.

Likely Respondents: Eligible applicants are schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit an application and are accredited for the provision of primary care nurse practitioner and nurse midwifery programs accredited by a national nurse education accrediting agency recognized by the Secretary of the U.S. Department of Education. The school must be located in the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, Guam, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.