normalization factors between FY 2006 and FY 2007.

Note: If there is no value or dashes (that is, ''----'') in either the geometric mean LOS or the arithmetic mean LOS columns, the volume of cases is insufficient to determine a meaningful computation of these statistics.

IV. Discussion of Effective Date and Notice and Comment Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). In addition, a final rule would ordinarily require a 30-day delay in effective date after the date of publication in the **Federal Register**. This correction of the rates published in the FY 2007 IPPS notice does not constitute a rule under the Administrative Procedure Act, because, in our FY 2007 IPPS final rule (71 FR 47870, August 18, 2006), we already published the methodologies and formulas we use for determining the wage index, geographic adjustment factors, and other rates. This notice does not change our methodology or formulas, but merely ensures that our rules are implemented correctly. As this notice is not a rule under the Administrative Procedure Act, no notice of proposed rulemaking or delay in effective date is necessary.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: December 28, 2006.

Ashley Files Flory,

Deputy Executive Secretary to the Department.

[FR Doc. 06–9976 Filed 12–29–06; 1:29 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0525]

Supplements and Other Changes to an Approved Application; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments on issues that FDA should consider when developing revisions to its regulations regarding chemistry, manufacturing, and controls (CMC) supplements and other changes to approved marketing applications for human drugs. FDA is evaluating how it could revise its regulations to allow for consideration of risk-based approaches based on manufacturing process understanding, including prior knowledge of similar products, and overall quality systems to provide an enhanced risk-based approach to the CMC regulatory process, which would reduce the number of supplements. We will consider the input from the public meeting and comments on the issues presented in this document as we consider whether to revise our regulations.

DATES: The public meeting will be held on February 7, 2007, from 8:30 a.m. to 3:30 p.m. Anyone who wishes to speak at the meeting must register and submit a summary of the presentation by January 24, 2007, and submit an electronic copy of the presentation by January 31, 2007. See section III of the **SUPPLEMENTARY INFORMATION** section of this document for details on how to register. Submit written or electronic comments by March 7, 2007.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Drug Evaluation and Research Conference Room, 7519 Standish Pl., third floor, rm. A, Rockville, MD 20855. There is parking near the building. Photo identification is required to clear building security.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: David J. Cummings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3525, Rockville, MD 20993–0002, 301–796–2400, e-mail: *David.Cummings@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 28, 1999 (64 FR 34608), FDA published a proposed rule to implement section 116 of the Food and Drug Administration Modernization Act (FDAMA)[1] by amending certain regulations including § 314.70 (21 CFR 314.70) regarding supplements and other changes to approved human new drug and abbreviated new drug marketing applications. In the **Federal Register** of April 8, 2004 (69 FR 18728), FDA published the final rule (final rule) implementing these changes. Section 314.70, as amended, requires manufacturers to assess the effects of manufacturing changes on the identity, strength, quality, purity, and potency of a drug as those factors relate to the safety or effectiveness of the product, and categorizes all changes beyond the established variations in an approved NDA or ANDA into one of three groups—major, moderate, or minor. Major changes require an applicant to submit and receive FDA approval of a supplement before distribution of the product made with the manufacturing change. Moderate changes require an applicant to submit a supplement at least 30 days before distribution of the product or, in some cases, submit a supplement at the time of distribution. Minor changes require an applicant to notify FDA of the changes in an annual report.

In August 2002, FDA introduced the Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century Initiative (CGMP Initiative, available on the Internet at *http://www.fda.gov/cder/gmp/index.htm*) to enhance and modernize the regulation of pharmaceutical manufacturing and product quality. In September 2004 (after publication of the final rule), FDA published a final report on ''Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach'' (*http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm*). As explained in the report, FDA regulates pharmaceutical manufacturing to ensure that the drug supply in the United States is of consistently high quality. Because of critical public health implications of drug manufacturing, FDA traditionally has exercised extensive control over virtually every aspect of the manufacturing process. This regulatory approach has contributed to pharmaceutical companies being reluctant to change their manufacturing processes and equipment. In recent years, significant advances in pharmaceutical manufacturing science, modern quality management systems, and risk management approaches have taken place. This has yielded new tools that

[1] Section 116 of FDAMA (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (FDCA) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to certain approved marketing applications, including new drug applications (NDAs) and abbreviated new drug applications (ANDAs).

can be used to help ensure manufacturing quality. The new tools enable manufacturers to detect, analyze, correct, and prevent problems and continuously improve their manufacturing processes. It has been the goal of the CGMP Initiative to create a regulatory paradigm that will encourage pharmaceutical manufacturers to use these new tools to facilitate their decision making and implementation of manufacturing processes to reliably produce pharmaceuticals of high quality. Under the new paradigm, as under the current scheme, pharmaceutical manufacturers are ultimately responsible for ensuring the quality of their products subject to FDA regulatory oversight.

The current § 314.70 categorizes postapproval CMC changes and their associated reporting requirements without consideration of the applicant's risk management activities or internal quality systems and practices; therefore, § 314.70 reflects a rules-based, or prescriptive, approach to regulating postapproval manufacturing changes. The current § 314.70 may create regulatory burdens and costs that discourage beneficial manufacturing changes and may not support a desirable level of innovation, modernization, and flexibility for the industry as described in the CGMP Initiative.

Consistent with the agency's risk-based approach to regulating pharmaceutical manufacturing described in the CGMP Initiative, FDA is considering possible revisions to § 314.70. In particular, FDA is evaluating how it could revise § 314.70 to allow for more manufacturing changes to be made without prior FDA approval using a firm's internal change control system. FDA also is evaluating how it could revise § 314.70 to allow for consideration of risk-based approaches based on manufacturing process understanding, including prior knowledge of similar products, and overall quality systems to provide an enhanced risk-based approach to the CMC regulatory process. To accomplish this objective, FDA is considering redefining what FDA considers to be a major manufacturing change, reducing the reporting burden for certain changes, and creating a new reporting category of manufacturing changes that do not require notification to FDA. FDA anticipates that these revisions would reduce the number of postapproval supplements that are required to be submitted. We emphasize that under a new regulatory scheme, although the reporting burdens for certain manufacturing changes would be reduced, manufacturers will continue to be responsible for ensuring product quality. FDA also is considering an approach that would retain aspects of the current regulatory scheme to accommodate those manufacturers who choose to continue operating within the current regulatory framework. FDA is announcing this public meeting to solicit comments on issues that should be considered if FDA decides to propose revisions to § 314.70.

II. Questions for Discussion and Comment

FDA has prepared the following questions to help focus the comments that will be presented at the public meeting or otherwise communicated to the agency. Those who comment are invited to address any or all of these questions, or raise other issues.

1. Is it valuable for the agency to move toward a more risk-based and quality systems oriented strategy for regulating postapproval CMC changes outside of the formal application review process? What are the advantages and/or disadvantages?

2. Would revising § 314.70 as described in this notice provide the same level of protection to the public as the current regulatory scheme with respect to ensuring the safety and efficacy of human drugs? What inspectional approaches might the agency consider to evaluate manufacturing changes while ensuring public safety?

3. Would revising § 314.70 as described in this notice change the regulatory burden on the pharmaceutical industry? If so, how would the burden change?

4. Would reducing the prescriptiveness of § 314.70 provide manufacturers with greater regulatory flexibility? Would it encourage manufacturers to adopt CMC-related risk management strategies? Would there be disadvantages?

III. Registration, Agenda, and Transcript

Seating is limited and will be available on a first-come, first-served basis. If you need special accommodations because of a disability, please inform David J. Cummings.

Registration for Speaking Attendees: If you wish to make an oral presentation at the meeting, you must register and submit a summary of your presentation to David J. Cummings by January 24, 2007, via e-mail to: *David.Cummings@fda.hhs.gov*. When registering, you must provide the following information: (1) The specific topic or issue to be addressed; (2) your name, title, company or organization, address, phone number, and e-mail address; and (3) the approximate time requested to speak. FDA encourages persons and groups having similar interests to consolidate their information for presentation through a single representative. After reviewing the requests to present, we will notify each participant by e-mail or telephone of the amount of time allotted and the approximate time the participant's presentation is scheduled to begin. Presenters must send electronic copies of their presentations in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to David J. Cummings by noon on January 31, 2007.

Agenda and Transcript: The agenda for the public meeting will be available February 2, 2006, on FDA's Center for Drug Evaluation and Research (CDER) Web site at: *http://www.fda.gov/cder/meeting/OPS_20070207.htm*. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in the heading of this document and on CDER's Web site identified previously.

You may examine the meeting transcript Monday through Friday between 9 a.m. and 4 p.m. in the Division of Dockets Management Public Reading Room (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*. You may also request a copy of the transcript from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page or on compact disc at a cost of $14.25 each.

IV. Comments

Regardless of attendance at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to the questions and the focus of this public meeting by March 7, 2007. All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The received comments are available for public examination in the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–22588 Filed 1–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

United States Visitor and Immigrant Status Indicator Technology (US–VISIT)

AGENCY: US–VISIT, Department of Homeland Security.

ACTION: Submission for OMB review; comment request.

SUMMARY: The Department of Homeland Security, US–VISIT Program, has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling Steve Yonkers, 202–298–5200 (this is not a toll free number).

DATES: Comments are encouraged and will be accepted until March 6, 2007. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Comments and questions about this Information Collection Request should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Homeland Security, Office of Management and Budget, Room 10235, Washington, DC 20503.

The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: Steve Yonkers, 202–298–5200 (this is not a toll free number).

Analysis

Agency: Department of Homeland Security, US–VISIT Program.

Title: US–VISIT Program.

OMB Number: 1600–0006.

Frequency: One-time collection.

Affected Public: Foreign visitors into the U.S.

Number of Respondents: 156,732,442.

Estimated Time Per Respondent: 15 seconds.

Total Burden Hours: 658,276 hours.

Total Burden Cost (capital/startup): $0.00.

Total Burden Cost (operating/maintaining): $0.00.

Description: The United States Visitor and Immigrant Status Indicator Technology (US–VISIT) is a program established by the Department of Homeland Security (DHS) to meet specific legislative mandates intended to strengthen border security, address critical needs in terms of providing decision makers with critical information, and demonstrate progress toward performance goals for national security, facilitation of trade and travel, and supporting immigration system improvements. US–VISIT represents a major achievement in creating an integrated border screening system that enhances our nation's security and efforts to reform our immigration and border management systems. Through US–VISIT, DHS is increasing our ability to manage the information collected about foreign visitors during the pre-entry, entry, status management, and departure processes, which allows us to conduct better analysis of that information, thereby strengthening the integrity of our immigration system.

Chase Garwood,

Chief Information Officer.

[FR Doc. 06–9987 Filed 12–29–06; 11:32 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request Approval From OMB of One New Public Collection of Information: Department of Homeland Security Traveler Redress Inquiry Program (DHS TRIP)

AGENCY: Transportation Security Administration, DHS.

ACTION: Notice.

SUMMARY: The Transportation Security Administration (TSA), as lead for DHS, invites public comment on a new information collection requirement abstracted below that we will submit to the Office of Management and Budget (OMB) for approval in compliance with the Paperwork Reduction Act.

DATES: Send your comments by March 6, 2007.

ADDRESSES: Comments may be mailed or delivered to Katrina Kletzly, Attorney-Advisor, Office of the Chief Counsel, TSA–2, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220.

FOR FURTHER INFORMATION CONTACT: Katrina Kletzly at the above address, or by telephone (571) 227–1995 or facsimile (571) 227–1381.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. Therefore, in preparation for OMB review and approval of the following information collection, TSA, on behalf of DHS, is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Purpose of Data Collection

The Rice-Chertoff Initiative (RCI) Department of Homeland Security Traveler Redress Inquiry Program (DHS TRIP) was developed as a voluntary program by DHS to provide a one-stop mechanism for individuals to request redress who believe they have been: (1) Denied or delayed boarding; (2) denied or delayed entry into or departure from the United States at a port of entry; or (3) identified for additional (secondary) screening at our Nation's transportation