License Number: 002853F.
Name: HPH International, Inc.
Address: 555 East Ocean Blvd., Ste. 217, Long Beach, CA 90802.
Date Revoked: December 8, 2009.
Reason: Surrendered license voluntarily.

License Number: 019598N.
Name: SCM Global, Inc.
Address: 1201 Corbin Street, Elizabeth, NJ 07201.
Date Revoked: November 30, 2009.
Reason: Surrendered license voluntarily.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. E9–30523 Filed 12–22–09; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) Title 44, United States Code (U.S.C.), as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Data Collection Tool for State Offices of Rural Health Grant Program: (OMB Number: 0915–0322)—Extension

The mission of the Office of Rural Health Policy (ORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Sec. 711 of the Social Security Act [42 U.S.C. 912]), Congress charged ORHP with administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.

In accordance with the Public Health Service Act, section 338J, 42 U.S.C. 254r, the Health Resources and Services Administration proposes to revise the State Offices of Rural Health Grant Program—Guidance and Forms for the Application. The guidance is used annually by 50 States in writing applications for Grants under the State Offices of Rural Health Grant Program (SORH) of the Public Health Service Act, and in preparing the required report.

ORHP seeks to expand the information gathered from grantees on their efforts to provide technical assistance to clients within their State. SORH grantees would be required to submit a Technical Assistance Report that includes: (1) The total number of technical assistance encounters provided directly by the grantee; and, (2) the total number of unduplicated clients that received direct technical assistance from the grantee. Submission of the Technical Assistance Report would be done via e-mail to ORHP no later than 30 days after the end of each 12-month budget period.

The estimated average annual burden is as follows:

Form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Technical Assistance Report	50	1	12.5	625
Total	50			625

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 17, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–30538 Filed 12–22–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0399]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 5 on Disintegration Test General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 5: Disintegration Test General Chapter.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Disintegration Test General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition.

The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. In the **Federal Register** of February 21, 2008 (73 FR 9575), FDA made available a guidance on the Q4B process entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.''

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments on the guidance 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002, 301–796–1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of August 5, 2008 (73 FR 45466), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 5: Disintegration Test General Chapter.'' The notice gave interested persons an opportunity to submit comments by October 6, 2008.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 5: Disintegration Test General Chapter'' was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2009.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Disintegration Test General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance. When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency'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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov*, *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

Dated: December 17, 2009.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning, and Budget.

[FR Doc. E9–30441 Filed 12–22–09; 8:45 am]

BILLING CODE 4160–01–S