only upon valid scientific evidence to determine whether there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness (see § 860.7(c)(2)).

According to § 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, under § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed in the **DATES** section of this document to the Division of Dockets Management (see **ADDRESSES**).

V. Paperwork Reduction Act of 1995

This order refers to collections of information necessary to comply with the requirements found in sections 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, subpart E or the requirements of 515(b) of the act (21 U.S.C. 360e(b)), 21 CFR part 860, and 21 CFR part 814. 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 860.123 have been approved under OMB control number 0910–0138; the collections of information in 21 CFR part 814, have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120.

Dated: April 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8022 Filed 4–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

The 12th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference; ''Regulatory Affairs: The Challenges of Ensuring Product Safety''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following conference: 12th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the Drug, Device, and Biologics industries with an opportunity to interact with FDA reviewers and compliance officers from the Centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answers, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 9 and 10, 2009, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott Hotel, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949–608–4413, FAX: 949–608–4417, or OCRA, Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, 949–387–9046, FAX: 949–387–9047, Web site: *http://www.ocra-dg.org*.

Registration and Meeting Information: See OCRA Web site, *http://www.ocra-dg.org*. Contact Attention to Detail at 949–387–9046.

Before May 8, 2009, registration fees are as follows: $675.00 for members, $725.00 for nonmembers and $475.00 for FDA/Govt/Students.[1] After May 8, 2009, $725.00 for members, $775.00 for nonmembers, and $475.00 for FDA/Govt/Students.[1]

The registration fee will cover actual expenses including refreshments, lunch, materials, parking, and speaker expenses.

If you need special accommodations due to a disability, please contact Linda Hartley at least 10 days in advance.

Dated: April 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8135 Filed 4–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management

[1] OCRA Student Rate applies to those individuals enrolled in a Regulatory or Quality related academic program at an accredited institution. Proof of enrollment required.