

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Submission of information for Pre-Submission Program	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per respondent (in hours)	Total hours
CDRH	2465	1	2465	137	337,705
CBER	79	1	79	137	10,823
Total	2544	1	2544	137	348,528

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA estimates that it will receive approximately 2544 pre-submission packages annually. The Agency reached this estimate by reviewing the number of submissions received by the Agency under the Pre-IDE program over the past 10 years. Based on FDA's experience with the Pre-IDE program, FDA expects the Pre-

Submission program to continue to be utilized as a viable program in the future and expects that the number of pre-submission packages will increase over its current rate and reach a steady state of approximately 2544 submissions per year.

FDA estimates from past experience with the Pre-IDE program that the complete process involved with the program takes approximately 137 hours.

This average is based upon estimates by FDA administrative and technical staff that is familiar with the requirements for submission of a Pre-Submission and related materials, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 348,528 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

Number of respondents	Total burden hours annualized	Hourly wage rate	Total cost annualized
2544	137	\$150	\$52,279,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The average to industry per hour for this type of work is \$150, resulting in a cost of \$20,550 per respondent. The estimated submission cost of \$20,550 multiplied by 2544 submissions per year equals \$52,279,200, which is the aggregated industry reporting cost annualized.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 803 are approved under OMB control number 0910-0437; the collections of information in 21 CFR part 807, subpart E is approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Division of Dockets Management (see *Comments*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Please see 21 CFR 812.3(m) and FDA's Web page on Clinical Trials, available at www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0563]

Single-Ingredient, Immediate-Release Drug Products Containing Oxycodone for Oral Administration and Labeled for Human Use; Enforcement Action Dates; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 6, 2012 (77 FR 40069). The document announced FDA's intention to take enforcement action against all unapproved single-ingredient, immediate-release drug products that contain oxycodone hydrochloride for oral administration and are labeled for human use, and persons who manufacture or cause the manufacture or distribution of such products in interstate commerce. The document was published with an incorrect Web link. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:
Astrid Lopez-Goldberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5368, Silver Spring, MD 20993-0002, 301-796-3485, *astrid.lopezgoldberg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012-16475, appearing on page 40069 in the **Federal Register** of Friday, July 06, 2012, the following correction is made:

1. On page 40070, in the first column, in the last paragraph, the Web link “<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm>” is corrected to read “<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#narcotics>”.

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-17089 Filed 7-12-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration/Xavier University Global Outsourcing Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled “FDA/Xavier University Global Outsourcing Conference.” This public conference for the pharmaceutical industry is in direct alignment with the “FDA Strategic Priorities 2011-2015,” and includes presentations from key FDA officials, global regulators, and industry experts. This conference drives collaboration on the topic of global outsourcing compliance by bringing pharmaceutical/biotechnology companies and contract partners to the same event to address the issues that reside on both sides of the contract. Expert presentations address the “how to” aspects of improving outsourced product quality through topics such as FDA International Initiatives, FDA Inspection Trends, Supply Chain Development, Quality Agreements, Supplier Qualification, and many more. The

experience level of our audience has fostered engaged dialogue that has led to innovative initiatives.

Dates and Times: The public conference will be held on September 24, 2012, from 8:30 a.m. to 5 p.m.; September 25, 2012, from 8:30 a.m. to 5:30 p.m.; and September 26, 2012, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

Contact Persons:

For information regarding this notice: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East Seventh Street, Cincinnati, OH 45202, 513-246-4134, email: *steven.eastham@fda.hhs.gov*.

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, email: *phillipsm4@xavier.edu*.

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2 1/2 days of the conference. Early registration ends August 5, 2012. Standard registration ends September 2, 2012. Late registration occurs September 3 to September 23, 2012. There will also be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES ¹

Attendee	Fee on or before August 5th	Fee August 6th–September 2nd	Fee September 3rd–September 23rd
Industry	\$995	\$1,295	\$1,495
Small Business (<100 employees)	800	900	1,000
Consultants	500	600	700
Startup Manufacturers/Academic	200	250	300
Media/Government	Free	Free	Free

¹ The fourth registration from the same company is free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the “Register Now” link on the conference Web site at <http://www.XavierGOC.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Sue

Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West Fifth St., Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the “Venue & Logistics” link at <http://www.XavierGOC.com> to make reservations. The hotel is expected to sell out during this timeframe, so early reservation in the conference room-block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA’s important mission to protect the public health. The conference will provide those engaged in FDA-regulated outsourcing with information on the following topics:

- FDA International Initiatives
- European Union Regulator Perspective