EXHIBIT 2.—ESTIMATED ANNUALIZED COST BURDEN—Continued

Data collection mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Post-intervention survey of clinicians and staff(2)	20	50	28	1,400
Control survey of clinicians and staff(2)	5	12.5	28	350
Chart audits(3)	25	208.33	10	2,083.33
Patient Focus Groups (post-intervention)(1)	80	160	12.54	2,006.40
Total	7,740	1,978.33		29,844.73

(1) Patient average hourly wage based on the average per capita income of $26,088 (computed into an hourly wage rate of $12.54) in Lehigh Valley, Pennsylvania: ''Demographic Information for the Lehigh Valley'' from the Lehigh Valley Economic Development Corporation 2006.

(2) Provider and practice hourly wage based on an average of the following estimates from LVPHO: physician = $70/hour; manager = $19/hour; clinical staff = $13/hour; and clerical staff = $10/hour.

(3) Practice clerical staff will retrieve the charts to be audited by study personnel; therefore only the time of the practice staff is included in Exhibit 1 and in the Exhibit 2 cost estimate. Practice clerical staff hourly wage is estimated by LVPHO to be $10/hour.

Estimated Annual Costs to the Federal Government

The estimated total cost to the Federal government is $271,764.68. The average annualized cost over the two years of the project is $135,882.34 per year. Exhibit 3 shows a breakdown of the costs.

EXHIBIT 3.—ESTIMATED ANNUAL COSTS TO THE FEDERAL GOVERNMENT

Component	Year 1	Year 2	Total
The cost of developing the data collection instruments	$24,765.38	$0	$24,765.38
The cost of implementing the data collections	99,061.52	24,601.75	123,663.27
The cost of analyzing the data and publishing the results	49,530.76	73,805.26	123,336.02
Total	173,357.66	98,407.02	271,764.68

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 20, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–6073 Filed 3–26–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0180]

Draft Guidance for Industry on Coronary Drug Eluting Stents–Nonclinical and Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Coronary Drug Eluting Stents—Nonclinical and Clinical Studies.'' This draft guidance is intended to provide recommendations to sponsors or applicants planning to develop, or to submit to FDA, a marketing application for a coronary drug eluting stent (DES). The draft guidance discusses the clinical studies that should be performed and the data that should be submitted to support such an application. The draft guidance is being issued in two parts. The companion document provides additional and more detailed guidance on some of the recommendations included in this document. The companion document is intended to be used together with this draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 25, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Ashley Boam, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4222, or

Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20903–0002, 301–796–1128.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Coronary Drug Eluting Stents—Nonclinical and Clinical Studies.'' Coronary stents are implantable devices that are placed percutaneously in one or more coronary arteries to maintain patency. As defined by section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), DESs are considered combination products because they are a combination of two different types of regulated components (a device and a drug) that are physically and/or chemically combined and produced as a single entity (21 CFR 3.2(e)(1)). A combination product is assigned to an agency component, such as the Center for Devices and Radiological Health (CDRH) or the Center for Drug Evaluation and Research (CDER) for premarket review and regulation based on a determination of the product's *primary mode of action*. In response to *several requests for designation* under 21 CFR 3.7, the agency determined that the primary mode of action for current DESs is that of the device component in maintaining coronary artery patency; the drug component plays a secondary role in preventing restenosis, augmenting the safety and/or effectiveness of the uncoated (bare) stent.[1] Therefore, the premarket review and regulatory responsibility has been assigned to CDRH. Nevertheless, careful consideration should be given to characterizing the drug component of DESs. This draft guidance is intended to provide recommendations on meeting the regulatory requirements for both the drug and device components of a DES.

DESs incorporate a pharmacologically active agent (drug) that is delivered at the site of stent deployment to reduce the incidence of restenosis due to neointimal hyperplasia associated with bare metal stenting. In many cases, the drug is incorporated into and released from a polymeric coating of sufficient capacity to accommodate the selected dose and to modulate its delivery at the intended site of action and for the intended duration. The chemical, physical, and mechanical attributes of the polymer coating system are important for stent deployment, biocompatibility, and stability. To perform a regulatory assessment of a DES, FDA must review data from a comprehensive evaluation of individual components (drug, polymer, and stent), as well as from a comprehensive evaluation of the finished drug-device combination product.

This draft guidance clarifies a number of issues related to the development DESs including the following.

- How to characterize the drug substance, including chemistry, nonclinical systemic and local tissue pharmacology and toxicology, and how to evaluate potential for and consequences of systemic clinical exposure.
- How to characterize the drug-device combination product, including the chemical/physical/mechanical properties of the DES, the nonclinical local vascular and regional myocardial toxicology, and the clinical performance of the drug-stent combination.
- Regulatory considerations that are unique to DES combination products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 part 211 (current good manufacturing practice for finished pharmaceuticals) have been approved under OMB control number 0910–0139. The collections of information in 21 CFR parts 312 (investigational new drug application) and 314 (applications for FDA approval to market a new drug) have been approved under OMB control numbers 0910–0014 and 0910–0001. The collections of information in FDA's medical devices regulations in 21 CFR parts 801 (labeling), 803 (medical device reporting), 812 (investigational device exemptions), 814 (premarket approval of medical devices), and 820 (quality system regulation) have been approved under OMB control numbers 0910–0485, 0910–0437, 0910–0078, 0910–0231, and 0910–0073.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 21, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6210 Filed 3–26–08; 8:45 am]

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[1] See ''Jurisdictional Update: Drug-Eluting Cardiovascular Stents,'' *http://www.fda.gov/oc/combination/stents.html*. This Jurisdictional Update is applicable to DESs for which the primary mode of action is the device component in maintaining vessel patency. However, a DES for which the primary mode of action is attributable to the drug component would be assigned to CDER.