we estimate the current annual per-product cost for innovator and generic products as $1,429 and $859, respectively. Therefore, we estimate that the total incremental printing costs for innovator and generic products are approximately $1.1 million and $1.6 million, respectively, over the 5-year period of the program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN OVER A 5-YEAR PERIOD [1]

Prescription drug labeling improvement and enhancement initiative	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total hours	Total capital costs ($million)	Total operating and maintenance costs ($million)
Submitting a supplement to FDA for the proposed PLR format labeling	375	2	750	196	147,000	$4.0	$1.1
Submitting a labeling supplement to FDA for generic drug products affected by the RLD labeling change	233	8	1,864	27	50,328	10.1	1.6
Total					197,328	14.1	2.7

[1] Numbers may not sum due to rounding.

Dated: May 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10414 Filed 5–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements.'' This study will investigate the impact of price comparison information in direct-to-consumer (DTC) and health care professional advertising for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by July 7, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements—(OMB Control Number 0910—NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

By their very nature, medical and health decisions are comparative (e.g., treat versus not treat). For consumers, these decisions may include the use of prescription drug products versus over the counter products versus herbal

supplements, as well as one prescription brand versus another prescription brand. Similarly, advertising is often comparative. In prescription drug advertising, sponsors are permitted to include truthful, non-misleading information about the price of their products in promotion. This may extend to price comparison information, wherein sponsors may include information about the price of a competing product in order to make advantageous claims. Currently, when price comparisons are made, the ad should also include context that the two drugs may not be comparable in terms of efficacy and safety and that the acquisition costs presented do not necessarily reflect the actual prices paid by consumers, pharmacies, or third party payers. Despite the inclusion of this additional information, there is concern that adding contextual information about efficacy or safety is not sufficient to correct the impression that the products are interchangeable and that price is the main factor to consider. The Office of Prescription Drug Promotion (OPDP) plans to investigate, through empirical research, the impact of price comparison information and additional contextual information on prescription drug product perceptions. This will be investigated in DTC and healthcare-directed professional advertising for prescription drugs.

We will investigate perceptions about overall drug safety and efficacy and perceptions of the comparator product. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described in this document, we will have sufficient power to detect small-to-medium sized effects in the main study.

Participants will be consumers who self-identify as having been diagnosed with diabetes and physicians who are General Practitioners (e.g., Family Practice, General Practice, Internal Medicine) and Specialists (e.g., Endocrinology, Pain Management). All participants will be 18 years of age or older. We will exclude individuals from the consumer sample who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take approximately 30 minutes.

Physician and consumer participants will be randomly assigned to view one of three possible versions of an ad (DTC or professional), as depicted in table 1. One version will present information about the price of the product relative to a competitor for the same indication (price comparison information). Another version will present this information with additional contextual information that the two drugs may not be comparable in terms of efficacy and safety and that the acquisition costs do not necessarily reflect actual prices paid. A third version will have a claim about the price of the product but will not present information about the price relative to a competitor, and will act as a control.

After viewing the ad, participants will respond to questions about information in the ad. Preliminary measures are designed to assess perception and understanding of product safety and efficacy; perception and understanding of the additional contextual information; perceptions of comparative safety and efficacy; and intention to seek more information about the product. The questionnaire is available upon request.

TABLE 1—STUDY DESIGN

Sample	Type of price comparison		
	Price information only	Price information + additional context	No comparison information (control)
Consumers (DTC ad) Physicians (Professional ad)	.....	.....	.....

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sample outgo (pretests and main survey)	41,110	.....	.....	.....	.....
Screener completes	7,400	1	7,400	.03 (2 minutes)	222
Eligible	4,933	.....	.....	.....	.....
Completes, Pretests Phase 1	400	1	400	0.5 (30 minutes)	200
Completes, Pretest Phase 2	1,000	1	1,000	0.5 (30 minutes)	500
Completes, Main Study	2,940	1	2,940	0.5 (30 minutes)	1,470
Total	.....	.....	.....	.....	2,392

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

Dated: May 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10410 Filed 5–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0589]

Draft Guidance for Industry on Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment; 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 ''Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antibacterial drugs for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). The science of clinical trial design and our understanding of this disease have advanced in recent years, and this draft guidance informs sponsors of our current recommendations for clinical development. FDA is specifically requesting comment on critical areas of scientific interest including the appropriate primary efficacy endpoints, the use of an intent-to-treat (ITT) population for the primary analysis population, and the use of antibacterial therapy by patients before participating in clinical trials. This draft guidance revises the draft guidance of the same name that published November 29, 2010.

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 either electronic or written comments on the draft guidance by August 5, 2014.

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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antibacterial drugs for the treatment of HABP/VABP. Issues in HABP/VABP clinical trials were discussed at a 2009 workshop cosponsored by FDA and professional societies. Recently, there have been additional discussions about clinical trial design and endpoints for HABP/VABP at a meeting of the Anti-Infective Drugs Advisory Committee. As a result of these public discussions, the science of clinical trial design and our understanding of endpoints and approaches to clinical development have advanced.

This draft guidance revises the draft guidance published in November 2010 (75 FR 73107) and informs sponsors of the changes in our recommendations. We acknowledge the challenges in conducting clinical trials of investigational antibacterial drugs in HABP/VABP. This revised draft guidance incorporates changes intended to attain a greater degree of balance between the practicability of conducting HABP/VABP clinical trials and the trial procedures needed for a scientifically sound and interpretable trial. We are requesting input from the public on these changes, for consideration before finalizing the guidance. Specifically, the changes from the 2010 draft guidance include:

- A description of two potential primary efficacy endpoints for HABP/VABP clinical trials: (1) All-cause mortality and (2) all-cause mortality or disease-related complications.
- A justification for a noninferiority margin based on all-cause mortality.
- Suggestions for efficacy analyses based on: (1) An overall ITT population and (2) a microbiological ITT population consisting of those patients who have a documented bacterial pathogen known to cause HABP/VABP.
- Recommendations for enrolling patients who have received prior effective antibacterial drug therapy.

Issuance of this guidance fulfills a portion of the requirements of title VIII, section 804 of the Food and Drug Administration Safety and Innovation Act of 2012 (Pub. L. 112–144), which requires FDA to ''review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs. . . .''

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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulation. 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 312 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*