

Data to Support Food and Nutrition Product Communications, as Used by the Food and Drug Administration—21 U.S.C. 393(d)(2)(D) (OMB Control Number 0910–NEW)

FDA plans to use the data collected under this generic clearance to inform its nutrition and foods communications campaigns. FDA expects the data to guide the formulation of its food and nutrition communication objectives. FDA also plans to use the data to help tailor print, broadcast, and use electronic media communications in order for them to have powerful and desired impacts on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

The information collected will serve two major purposes. First, as formative research, it will provide the critical knowledge needed about target

audiences. FDA must explore audiences' beliefs, perceptions, and decisionmaking processes about nutrition and food consumption in order to formulate the basic objectives of its risk communication campaigns. Such knowledge will provide the needed target audience understanding to design effective communication strategies, messages, and product labels. These communications will aim to improve public understanding of the risks and benefits of consuming certain foods or nutritional products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will give FDA some information about the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow

FDA to refine messages while still in the developmental stage. Respondents may be asked to give their reaction to the messages in individual or group settings.

FDA's Center of Food Safety and Applied Nutrition, Office of the Commissioner, and other Centers or Offices will use this mechanism to test messages about regulated food and nutrition products on a variety of subjects related to consumer, patient, or health care professional perceptions and use of foods and related materials, including but not limited to, food advertising, food and nutrition labeling, emerging risk communications, online sales of food products, and consumer and professional education. The data will not be used for the purposes of making policy or regulatory decisions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Individual indepth interviews	360	1	360	0.75	270
General public focus group interviews	144	1	144	1.5	216
Intercept interviews: central location	600	1	600	0.25	150
Intercept interviews: telephone	10,000 ²	1	10,000	0.08	800
Self-administered surveys	2,400	1	2,400	0.25	600
Gatekeeper reviews	400	1	400	0.50	200
Omnibus surveys	2,400	1	2,400	0.17	408
Total (general public)	16,304	16,304	2,644
Total physician focus group interviews	144	1	144	1.5	216
Total (overall)	2,860

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

² Brief interviews with callers to test messages, concepts and strategies following their call-in request to an FDA Center 1–800 number.

Annually, FDA projects about 30 communication studies using the variety of test methods listed in table 1. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: December 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 8, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room, (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings.” Please note that visitors to the White Oak Campus must enter through Bldg 1.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 31, rm. 2417, Silver Spring,

MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: kristine.khuc@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On March 8, 2011, the committee will discuss new drug application (NDA) 022-383, indacaterol maleate (ARCAPTA NEOHALER), by Novartis Pharmaceuticals Corp., for the long-term once daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 22, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February

11, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristine T. Khuc at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 21, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-32735 Filed 12-28-10; 8:45 am]

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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 OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Ryan White HIV/AIDS Program Allocation and Expenditure Forms (OMB No. 0915-0318)—[Extension]

The Ryan White HIV/AIDS Program Allocation and Expenditure Reports will enable the Health Resources and Services Administration's HIV/AIDS Bureau to track spending requirements for each program as outlined in the legislation. Grantees funded under Parts A, B, C, and D of the Ryan White HIV/AIDS Program (codified under Title XXVI of the Public Health Service Act) would be required to report financial data to HRSA at the beginning and end of their grant cycle.

All parts of the Ryan White HIV/AIDS Program specify HRSA's responsibilities in the administration of grant funds. Accurate allocation and expenditure records of the grantees receiving Ryan White HIV/AIDS Program funding are critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

The forms would require grantees to report on how funds are allocated and spent on core and non-core services, and on various program components, such as administration, planning, evaluation, and quality management. The two forms are identical in the types of information that are collected. However, the first report would track the allocation of the award at the beginning of the grant cycle and the second report would track actual expenditures (including carryover dollars) at the end of the grant cycle.

The primary purposes of these forms are to (1) provide information on the number of grant dollars spent on various services and program components, and (2) oversee compliance with the intent of Congressional appropriations in a timely manner. In addition to meeting the goal of accountability to the Congress, clients, advocacy groups, and the general public, information collected on these reports is critical for HRSA, state and local grantees, and individual providers for the evaluation of the effectiveness of these programs.

The response burden for grantees is estimated as: