uses an experimental design to assess consumer reactions to health claim language intended to convey both the potential health benefits and the level of scientific support for the health claim.

The comment also suggested that the information will not be useful if it is the agency's intent to alter or restrict the wording of qualified health claims because, according to the comment, consumers have the right to receive truthful information, regardless of whether they understand that information.

FDA disagrees. The agency has a responsibility to ensure that disclaimers and other qualifying language intended to prevent consumer deception are effective in serving that purpose. The study is designed to evaluate whether certain variants of the qualified health claims are more effective than others at conveying to consumers the potential health benefits and the level of scientific support for the health claim. FDA expects this study to be useful in determining language that effectively conveys this information to consumers.

The comment suggested that there might be ways to improve the quality or utility of the information collection, yet did not offer specific recommendations to modify the study and analysis. In particular, the comment expressed concern that an Internet survey cannot be used to measure consumer confusion.

FDA responds that the experimental study that is the basis of this information collection request is an Internet-based experiment, not an Internet survey. The experimental study is intended to assess the communication effects, in a large sample of study participants, of both existing health claim language that appears on dietary supplements and conventional food products and variants of such language. The study is not intended to measure consumer confusion per se.

One comment recommended that, to help maximize the quality, utility and accuracy of the data to be collected in the study, FDA should test the qualified claim language exactly as stated in the **Federal Register** notice published March 30, 2005.

FDA agrees. The experimental study will test the qualified claim language exactly as it appears in the notice, in addition to variants of the claim language.

A comment urged FDA to takes steps to ensure that using electronic data collection is reliable and verifiable for the study.

FDA is confident that the methodology is reliable and verifiable for this type of study. FDA will closely monitor the contractor that implements the experiment to ensure the validity and accuracy of the collected data.

Another comment supported FDA's efforts to understand consumer responses to food and dietary supplement labels, but expressed concern that FDA has not supplied sufficient information to evaluate whether the estimated burden of the proposed collection is accurate.

FDA believes that the estimate of burden is accurate because the estimate is based on past experience with Internet panel experiments similar in complexity and duration to the one proposed here. The study protocol will be available for public viewing when this 30-day notice is published. FDA has followed the procedures for public notice and comment about this information collection set out in the PRA (44 U.S.C. 3501–3520) and OMB regulations (5 CFR part 1320).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
30 (pre-test)	1	30	.16	5
7,440 (experiment)	1	7,440	.16	1,191
TOTAL				1,196

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

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7692 Filed 5–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0443]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Focus Groups as Used by the Food and Drug Administration'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 2006 (71 FR 9828), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0497. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7698 Filed 5–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0183]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on guidance on reagents for detection of specific novel influenza A viruses.

DATES: Submit written or electronic comments on the collection of information by July 21, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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, including each proposed extension of an existing 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.

Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR 866.3332—(OMB Control Number 0910–0584)—Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with 21 U.S.C. 360c(a)(1)(B), because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including post market surveillance, development and dissemination of guidance, recommendations, and ''other appropriate actions as the Secretary deems necessary'' (21 U.S.C. 360c(a)(1)(B)). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification will be codified in 21 CFR 866.3332, a regulation that will describe the new classification for reagents for detection of specific novel influenza A viruses and set forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation will refer to the special control guidance document, ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents.

The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available (from the World Health Organization, National Institutes of Health, and other public health entities), sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
10	2	20	10	200	$3,500

[1]There are no capital costs associated with this collection of information.

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year, estimated to take 10 hours. This results in a total data collection burden of 200 hours (10 x 20

= 200). FDA estimates that cost of developing standard operating procedures for each data collection is $350 (10 hours of work at $35/hour). This results in a total cost to industry of $3,500 ($350 x 10 respondents).

Dated: May 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7708 Filed 5–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0021]

International Conference on Harmonisation; Guidance on Q8 Pharmaceutical Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q8 Pharmaceutical Development.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes the suggested contents for the pharmaceutical development section of a regulatory submission in the ICH M4 Common Technical Document (CTD) format. The guidance also indicates areas where the provision of greater understanding of pharmaceutical and manufacturing sciences can create a basis for flexible regulatory approaches.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written comments on the 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.fda.gov/dockets/ecomments*. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Moheb Nasr, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, Bldg. 21, rm. 2630, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1900; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research; FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 9, 2005 (70 FR 6888), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q8: Pharmaceutical Development.'' The notice gave interested persons an opportunity to submit comments by April 11, 2005. To provide additional time for public comment consistent with the time for comment provided by other ICH regulatory agencies, FDA reopened the comment period until June 11, 2005 (70 FR 24819, May 11, 2005).

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2005.

The guidance describes the suggested contents for the pharmaceutical development section (section 3.2.P.2) of a regulatory submission in the CTD format for drug products as defined in the scope of module 3 of the CTD. The information and knowledge gained from pharmaceutical development studies provide scientific understanding to support the establishment of specifications and manufacturing controls. The guidance also indicates areas where the provision of greater understanding of pharmaceutical and manufacturing sciences can create a basis for flexible regulatory approaches.

This guidance applies to pharmaceutical studies as defined in section 3.2.P.2 of module 3 of the CTD. The guidance does not apply to submissions for drug products during the clinical research stages. However, the principles described in the guidance are important to consider during product development.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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