January 31, 2009, under OMB Control No. 3084-0134.

The FTC plans to continue sending information requests annually to the ultimate parent company of several of the largest cigarette companies and smokeless tobacco companies in the United States (''industry members''). The information requests will seek data regarding, *inter alia:* (1) the tobacco sales of industry members; (2) how much industry members spend advertising and promoting their tobacco products, and the specific amounts spent in each of a number of specified expenditure categories; (3) whether industry members are involved in the appearance of their tobacco products in television shows or movies; (4) how much industry members spend on advertising intended to reduce youth tobacco usage; (5) the events, if any, during which industry members' tobacco brands are televised; and (6) for the cigarette industry, the tar, nicotine, and carbon monoxide ratings of their cigarettes, to the extent they possess such data. The information will again be sought using compulsory process under Section 6(b) of the FTC Act.

Under the PRA, 44 U.S.C. 3501-3521, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3), 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the instant collection of information.

The FTC invites comments on: (1) whether the proposed collection of information required by the Rule is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Estimated hours burden: The FTC staff's estimate of the hours burden is based on the time required to respond to each information request. Although the FTC currently anticipates sending in 2009 information requests to the six largest cigarette companies and the five largest smokeless tobacco companies,[2] the burden estimate is based on up to 15 information requests being issued per year to take into account any future changes in these industries. These companies vary greatly in size, in the number of products that they sell, and in the extent and variety of their advertising and promotion. Prior input received from the industries, combined with staff's knowledge of them, suggests that the time most companies would require to gather, organize, format, and produce their responses would range from 30 to 80 hours per information request for the smaller companies, to as much as hundreds of hours for the very largest companies. As an approximation, staff continues to assume a per company average of 180 hours for the ten largest recipients of the Commission's information request to comply with it; cumulatively, 1,800 hours per year.[3] Staff further estimates that for the eleventh anticipated recipient of the information request to be issued in 2009 and the four possible additional recipients, all of which would be smaller companies, the burden should not exceed 60 hours per company or 300 hours, cumulatively. Thus, overall estimated burden for a maximum of 15 recipients of the information request is 2,100 hours. These estimates include any time spent by separately incorporated subsidiaries and other entities affiliated with the ultimate parent company that has received the information request.

Estimated cost burden: It is not possible to calculate with precision the labor costs associated with this data production, as they entail varying compensation levels of management and/or support staff among companies of different sizes. Financial, legal, marketing, and clerical personnel may be involved in the information collection process. Commission staff assumes that professional personnel will handle most of the tasks involved in gathering and producing responsive information, and have applied an average hourly wage of $150/hour for their combined labor. Staff's best estimate for the total labor costs for up to 15 information requests is $315,000. Staff believes that the capital or other non-labor costs associated with the information requests are minimal. Although the information requests may necessitate that industry members maintain the requested information provided to the Commission, they should already have in place the means to compile and maintain business records.

[2] In 2007, the Commission issued information requests to five cigarette companies and five smokeless tobacco companies. Given changing growth conditions in the industry since then, the Commission anticipates that it will issue requests to six cigarette companies in 2009.

[3] 70 FR 24415 (May 9, 2005); 70 FR 62313 (October 31, 2005).

William Blumenthal

General Counsel

[FR Doc. E8–18098 Filed 8–6–08: 8:45 am]

BILLING CODE 6750–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0063] (formerly Docket No. 2008N–0016)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Exports: Notification and Recordkeeping Requirements'' 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 Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane,Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 8, 2008 (73 FR 26119), 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 0910–0482. The approval expires on July 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: July 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18128 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0056] (formerly Docket No. 2004N–0234)

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to seek public comment on possible topics for future guidance document development or revisions of existing ones.

DATES: Submit comments on this list and on any agency guidance documents at any time.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2004–N–0056, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For general information regarding FDA's GGP policy contact*: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

For information regarding specific topics or guidances: Please see contact persons listed in the table in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA issued its final rule on GGPs (21 CFR 10.115). GGPs are intended to ensure involvement of the public in the development of guidance documents and to enhance understanding of the availability, nature, and legal effect of such guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publishing an annual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents (65 FR 56468 at 56477; 21 CFR 10.115(f)(5)).

The agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the agency is considering. The agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by topic categories. The agency's contact persons for each specific area are listed in the tables that follow.

II. Center for Biologics Evaluation and Research (CBER)

Title/Topic of Guidance	Contact
CATEGORY—BLOOD AND BLOOD COMPONENTS	Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210
Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion	Same as above (Do)
Assessment of Donors of Blood and Blood Components for Transfusion Transmitted Malaria Risk	Do
Use of Serological of Tests on Samples from Donors of Whole Blood and Blood Components for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection	Do
CATEGORY—VACCINES AND ALLERGENICS	
Considerations for the Development of Vaccines to Protect Against Global Infectious Diseases	Do