The burden estimates for the recordkeeping requirements in table 1 of this document are based on FDA's institutional experience regarding creation and review of such procedures and similar recordkeeping requirements, and data provided to FDA to prepare an economic analysis of the potential economic impact of the May 3, 1996, proposed rule entitled ''Current Good Manufacturing Practice: Proposed Amendment of Certain Requirements for Finished Pharmaceuticals'' (61 FR 20104). Annual SOP maintenance is estimated to involve 1 hour annually per SOP, totaling 25 hours annually per recordkeeper.

The May 3, 1996, proposed rule revising part 211 CGMP requirements would require additional SOPs. Cost estimates for those additional SOPs were included in the proposed rule, but are not included here. Any comments on those estimates will be evaluated in any final rule based on that proposal.

In the **Federal Register** of February 7, 2002 (67 FR 5825), the agency requested comments on the proposed collection of information. There were no comments received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOP Maintenance (See previous list of 25 SOPs)	4,184	1	4,184	25	104,600
New startup SOPs	100	25	2,500	20	50,000
211.34	4,184	.25	1,046	.5	523
211.67(c)	4,184	50	209,200	.25	52,300
211.68	4,184	2	8,368	1	8,368
211.68(a)	4,184	10	41,840	.5	20,920
211.68(b)	4,184	5	20,920	.25	5,230
211.72	4,184	.25	1,046	1	1,046
211.80(d)	4,184	.25	1,046	.1	105
211.100(b)	4,184	3	12,552	2	25,104
211.105(b)	4,184	.25	1,046	.25	262
211.122(c)	4,184	50	209,200	.25	52,300
211.130(e)	4,184	50	209,200	.25	52,300
211.132(c)	1,698	20	33,960	.5	16,980
211.132(d)	1,698	.2	340	.5	170
211.137	4,184	5	20,920	.5	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	.5	4,184
211.173	1.077	1	1,077	.25	269
211.180(e)	4,184	.2	837	.25	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	.25	2,092
211.184	4,184	3	12,552	.5	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368
211.194	4,184	25	104,600	.5	52,300
211.196	4,184	25	104,600	.25	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	.5	20,920
Total					848,625

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

Dated: May 8, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12263 Filed 5–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0209]

Request for Comment on First Amendment Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking public comment to ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law. Recent case law has emphasized the need for not imposing unnecessary restrictions on speech. FDA believes this action will help the agency continue to protect the public health, while giving full recognition to evolving judicial decisions.

DATES: Submit written or electronic comments on this notice by July 30, 2002. Responses to those comments must be submitted by September 13, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Catherine Lorraine, Office of Policy, Planning, and Legislation (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to protecting the public health as well as to free and open communication. Recent years have witnessed increased attention by consumers to their own medical care. The public's interest in, and access to, useful and truthful information about medical products have skyrocketed. This generally positive development presents unique challenges to the FDA, which regulates a wide range of both products and words.

FDA has historically employed its authority to ensure, to the extent possible, that health care professionals and consumers receive accurate and complete information. The manner and substantive content of FDA's regulation of speech has important implications for public health. False or misleading claims concerning foods, drugs, biologics, medical devices, cosmetics, or veterinary medicines may harm individuals who rely on those claims. Truthful claims, by contrast, may improve public health. At the same time, advertising may have indirect effects on public health. If advertising of prescription drugs, for instance, leads to better informed consumers or to more physician visits to treat under-diagnosed illnesses, more people will be better off. On the other hand, if advertising of prescription drugs results in the inappropriate prescription of pharmaceuticals, the effect on public health will be negative.

The Supreme Court has increasingly recognized the value of speech proposing a commercial transaction, which it calls ''commercial speech'' and which is entitled to First Amendment protection so long as it is truthful and not misleading. This case law presents a challenge to FDA. FDA must balance the need and right of Americans to speak and hear information vital to their every day lives against the need to ensure that people are not misled. The importance of FDA vigilance is heightened given the nature of many of the products FDA regulates, some of which are extremely complex and which have the potential to harm as well as help.

There may be tension between some aspects of FDA's authority and judicial developments. Some statutory provisions that FDA enforces explicitly limit speech. Indeed, much of the operation of the Federal Food, Drug, and Cosmetic Act (the act) depends on the use of words, such as whether a product is marketed along with claims that it can affect the structure or function of the body of man, or treat disease.

As recently as April 2002, however, the Supreme Court struck down as violative of the First Amendment legislative authority for the FDA to restrict advertising of particular compounded drugs. (*Thompson* v. *Western States Medical Center* , 535 U.S. _, No. 01–344 (April 29, 2002)). In that decision, the Court said that even assuming that the restriction on speech directly advanced the Government's important interest in maintaining the integrity of FDA's new drug approval process, that interest could have been attained without imposing such restrictions. Lower courts have also held that the FDA must adhere to the First Amendment's guarantee of free speech. Not only have some of these decisions thwarted actions FDA has wished to pursue, however beneficial as matters of public policy, but they may threaten to diminish the overall legal credibility necessary for FDA to sustain its authority to accomplish its important public health duties.

FDA must continue to pursue regulation of products for purposes of protecting the public with a full recognition of the evolving judicial landscape in areas that directly affect its ability to regulate words. To be sure, FDA will continue to regulate commercial speech as part of its mandate. In particular, FDA intends to defend the act against any constitutional challenges, as it did in the *Western States* case. FDA seeks to ensure, however, that its regulations, guidances, policies, and practices comply with the First Amendment. FDA also wishes to learn what empirical evidence exists concerning the effect of commercial speech on the public health, and whether its regulations in this field in fact advance public health.

To that end, FDA seeks comment on these and other issues related to the FDA's regulation of commercial speech. To facilitate this discussion, FDA sets forth some questions below. These questions are not meant to be exhaustive. Rather, they are meant to spur the public to provide FDA with comments that will help FDA safeguard the public health while fulfilling all its legal obligations. The public is encouraged to address these and/or other related questions.

1. Are there arguments for regulating speech about drugs more comprehensively than, for example, about dietary supplements? What must an administrative record contain to sustain such a position? In particular, could FDA sustain a position that certain promotional speech about drugs is inherently misleading, unless it complies with FDA requirements? Does anything turn on whether the speech is made to learned intermediaries or to consumers? What is the evidentiary basis of such a distinction?

2. Is FDA's current position regarding direct-to-consumer and other advertisements consistent with empirical research on the effects of those advertisements, as well as with relevant legal authority? What are the positive and negative effects, if any, of industry's promotion of prescription drugs, biologics, and/or devices? Does the current regulatory approach and its implementation by industry lead to over-prescription of drugs? Do they increase physician visits or patient compliance with medication regimes? Do they cause patient visits that lead to treatment for under-diagnosed diseases? Does FDA's current approach and its implementation by industry lead to adequate treatment for under-diagnosed diseases? Do they lead to adequate patient understanding of the potential risks associated with use of drugs? Does FDA's current approach and its implementation by industry create any impediments to the ability of doctors to give optimal medical advice or prescribe optimal treatment?

3. May FDA distinguish claims concerning conventional foods from those relating to dietary supplements, taking into account limits on claims that can be made about foods in the Nutrition Labeling and Education Act, 21 U.S.C. 301, 321, 337, 343, 371? What must an administrative record contain to sustain or deny claims on food labels? How can information best be presented in a succinct but non-misleading fashion? To what extent do assertions in claims need qualifications or disclaimers added to the label to avoid any misconceptions that consumers may draw? Is there a basis to believe that consumers approach claims about conventional foods and dietary supplements differently?

4. Should disclaimers be required to be in the same (or smaller or larger) size of type and given equal prominence with claims? Is there any relevant

authority or social science research on this issue?

5. How can warnings be made most effective in preventing harm while minimizing the chances of consumer confusion or inattention? Is there any evidence as to which types of warnings consumers follow or disregard?

6. What arguments or social science evidence, if any, can be used to support distinguishing between claims made in advertisements and those made on labels? Does the First Amendment and the relevant social science evidence afford the Government greater latitude over labels?

7. Would permitting speech by manufacturer, distributor, and marketer about off-label uses undermine the act's requirement that new uses must be approved by the FDA? If so, how? If not, why not? What is the extent of FDA's ability to regulate speech concerning off-label uses?

8. Do FDA's speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?

9. Are there any regulations, guidance, policies, and practices FDA should change, in light of governing First Amendment authority?

FDA is requesting comments within 75 days. Parties will then be given 45 days to reply to the comments of others. Parties are encouraged to share comments among themselves.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this notice by July 30, 2002. Responses to those comments must be submitted by September 13, 2002. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Submit one electronic 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 13, 2002.

William Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 02–12325 Filed 5–13–02; 4:53 pm]

BILLING CODE 4160–01–S

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, 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, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Application for Certification and Recertification as a Federally Qualified Health Center (FQHC) Look-Alike (OMB No. 0915–0142): Revision

The Health Resources and Services Administration (HRSA) revised the application guide used by organizations applying for certification or recertificaion as a Federally Qualified Health Center (FQHC) Look-Alike for purposes of cost-based reimbursement under the Medicaid and Medicare programs. The guide's revision will reflect legislative, policy, and technical changes since October 1999, the issuance date of the last guidance. The revisions include reference to the Medicare, Medicaid and State Children's Health Insurance Program Benefits Improvement and Protection Act (BIPA) of 2000, section 702, the Medicaid prospective payment system for FQHCs, the elimination of waiver allowances under the Medicaid FQHC benefit and the interpretation and implementation of policy documents issued by HRSA.

The estimated burden is as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	25	1	100	2,500
Recertification	75	1	20	1,500
Total	100	.....	.....	4,000

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 8, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–12258 Filed 5–15–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Non-Mammalian Organisms as Models for Anticancer Drug Discovery.

Date: June 13–14, 2002.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Lalita D Palekar, PhD, Scientific Review Administrator, Special