101.70(f) (21 CFR 101.70(f)) sets forth the information a person is required to supply in such a petition. This information will be used by the agency in determining whether a petition meets the requirements for issuing a regulation authorizing a health claim, thereby ensuring that the public health is protected. The respondents for this collection are businesses, other for-profit organizations, or not-for-profit organizations.

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

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
101.70(f)	3	1	3	80	240	?	?

Where question marks (?) appear, FDA has no information on which to determine whether there are capital costs or operating and maintenance costs associated with this collection. FDA is asking for comments on the extent to which there are capital costs or operating and maintenance costs associated with this collection.

FDA has estimated the average costs and burdens above based on its experience with health claim petitions that have been submitted to the agency. In the more than 3 years since § 101.70(f) became effective, FDA has received less than 10 health claims petitions. The hour burden is based on FDA's estimate of the average amount of time required to prepare these petitions.

4. Petitions for Nutrient Content Claims—21 CFR 101.69(m), (n), and (o) (OMB Control No. 0910–0288—Reinstatement)

Section 403(r)(4) of the act provides for the submission of petitions to FDA requesting the issuance of regulations authorizing a nutrient content claim characterizing the amount of a nutrient in a food product. Section 101.69(m)(1), (n)(1), and (o)(1) (21 CFR 101.69(m)(1), (n)(1), and (o)(1)) sets forth data requirements specific for nutrient content claims petitions, synonym petitions, and brand-name petitions, respectively. This information is used by FDA in determining whether a petition meets the requirements of the regulations for the issuance of a regulation providing for a nutrient content claim. The respondents for this collection are businesses, other for-profit organizations, or not-for-profit organizations.

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

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
101.69(m)(1)	1	1	1	40	40	?	?
101.69(n)(1)	1	1	1	20	20	?	?
101.69(o)(1)	1	1	1	20	20	?	?
Totals					80	?	?

Where question marks (?) appear, FDA has no information on which to determine whether there are capital costs or operating and maintenance costs associated with this collection. FDA is asking for comments on the extent to which there are capital costs or operating and maintenance costs associated with this collection.

FDA has estimated the average costs and burdens above based on its experience with nutrient content claim petitions that have been submitted to the agency. In the more than 2 years since § 101.69(m), (n), and (o) became effective, FDA has received only one nutrient content claim petition under § 101.69(n). The hour burden is based on FDA's estimate of the average amount of time required to prepare that petition. The hour burden for § 101.69(m) and (o) is based on the assumption that one petition would be submitted under each provision and that the information requirements are more complex (§ 101.69(m)) or about the same (§ 101.69(o)) as for § 101.69(n)).

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32034 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0393]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

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, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on MEDWATCH medical product reporting program forms, FDA form 3500 and 3500A.

DATES: Submit written comments on the collection of information by February 18, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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 Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, 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 reinstatement 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 listed below.

With respect to the following collection of information, FDA invites comments on: (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.

MEDWATCH—FDA's Medical Products Reporting Program, Forms FDA 3500 and FDA 3500A—21 CFR 310.305, 314.80, 600.80, 803.30, 803.50, 803.53, 803.56 (OMB Control Number 0910–0291—Reinstatement)

Under sections 505, 507, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act); (21 U.S.C. 355, 357, 360b, 360c, 360e, and 393) and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(f)(2)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling. To carry out its responsibilities, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information, will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action ranging from labeling changes to the rare product withdrawal. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR 310.305, 314.80, 600.80, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with all medications, devices, and biologics, as well as any other products that are regulated by FDA, two very similar forms are used. These forms replaced all other forms used by the agency, including Form FDA 1639. Form FDA 3500A is used for mandatory reporting. Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events and product problems by health professionals.

Respondents to this collection of information are health professionals, hospitals, and other health care providers (i.e., nursing homes, etc.), manufacturers of biologics, drugs, and medical devices, user facilities, distributors, and importers.

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

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CBER:					
600.80					
Form 3500	993	1	993	0.5	496.5
Form 3500A	63	188.7	11,889	1.0	11,889
CDER:					
310.305 and 314.80					
Form 3500	19,922	1	19,922	0.5	9,961
Form 3500A	500	303.0	151,513	1.0	151,513
CDRH:					
803.30, 803.50, 803.53, and 803.56					
Form 3500	4,572	1	4,572	0.5	2,286
Form 3500A	39,889	2.8	110,933	1.0	110,933
CFSAN:					
Form 3500	410	1	410	0.5	205
Form 3500A	0	0	0	0	0
Total Hours					287,283.5

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

(Note: Center for Biologics Evaluation and Research (CBER); Center for Drug Evaluation and Research (CDER); Center for Devices and Radiological Health (CDRH); and Center for Food Safety and Applied Nutrition (CFSAN).

As more medical products are approved by FDA and marketed, and as knowledge increases regarding the

importance of notifying FDA when adverse events and product problems are observed, it is expected that more reports will be submitted. The figures shown in the table are based on previously calculated estimates and actual 1995 reporting experiences. The number of reports recorded above were annualized based on actual 1995 experience and an anticipated 10-percent-per-year increase in reporting over the next 3 years. There are zeroes in the CFSAN row because mandatory reporting using Form FDA 3500A is not required.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32070 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0380]

Determination of Regulatory Review Period for Purposes of Patent Extension; VISTIDE™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VISTIDE™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VISTIDE™ (cidofovir). VISTIDE™ is indicated for the treatment of CMV retinitis in patients with acquired immune deficiency syndrome (AIDS). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VISTIDE™ (U.S. Patent No. 5,142,051) from the Institute of Organic Chemistry & Biochemistry of the Academy of Science of the Czech Republic and Rega Institut, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VISTIDE™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VISTIDE™ is 1,533 days. Of this time, 1,266 days occurred during the testing phase of the regulatory review period, while 267 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: April 17, 1992. The applicant claims April 16, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND's effective date was April 17, 1992, which was 30 days after FDA received the IND on March 18, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: October 4, 1995. The applicant claims September 29, 1995, as the date the new drug application (NDA) for VISTIDE™ (NDA 20–638) was initially submitted. However, FDA records indicate that NDA 20–638 was submitted on October 4, 1995.

3. *The date the application was approved*: June 26, 1996. FDA has verified the applicant's claim that NDA 20–638 was approved on June 26, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, the applicant seeks 305 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 18, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 17, 1997 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–32033 Filed 12–17–96; 8:45 am]

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