Statewide Assessment; CFSR On-site Review; CFSR Program Improvement Plan; and Anti-Discrimination Enforcement Corrective Action Plan. The collection of information for review of Federal payments to States for foster care maintenance payments (45 CFR 1356.71(i)) is authorized by title IV–E of the Social Security Act (the Act), section 474 [42 U.S.C. 674]. The Foster Care Eligibility Reviews (FCER) ensure that States claim title IV–E funds only on behalf of title IV–E eligible children. The collection of information for review of State child and family services programs (45 CFR 1355.33(b), 1355.33(c) and 1355.35(a)) is to determine whether such programs are in substantial conformity with State plan requirements under parts B and E of the Act and is authorized by section 1123(a) [42 U.S.C 1320a–1a] of the Act. The CFSR looks at the outcomes related to safety, permanency and well-being of children served by the child welfare system and at seven systemic factors that support the outcomes. Section 474(d) of the Act [42 U.S.C 674] deploys enforcement provisions (45 CFR 1355.38(b) and (c)) for the requirements at section 4371(a)(18) [42 U.S.C 671], which prohibit the delay or denial of foster and adoptive placements based on the race, color, or national origin of any of the individuals involved. The enforcement provisions include the execution and completion of corrective action plans when a State is in violation of section 471(a)(18) of the Act. The information collection is needed: (1) To ensure compliance with title IV–E foster care eligibility requirements; (2) to monitor State plan requirements under titles IV–B and IV–E of the Act, as required by Federal statute; and (3) to enforce the title IV–E anti-discrimination requirements through State corrective action plans. The resultant information will allow ACF to determine if States are in compliance with State plan requirements and are achieving desired outcomes for children and families, help ensure that claims by States for title IV–E funds are made only on behalf of title IV–E eligible children, and require States to revise applicable statutes, rules, policies and procedures, and provide proper training to staff, through the development and implementation of corrective action plans. These reviews not only address compliance with eligibility requirements but also assist States in enhancing the capacities to serve children and families. In computing the number of burden hours for this information collection, ACF based the annual burden estimates on ACF's and States' experiences in conducting reviews and developing program improvement plans.

Respondents: State Title IV–B and Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 1356.7 (i) Program Improvement Plan (FCER)	7	1	90	630
45 CFR 1366.33 (b) Statewide Assessment (CFSR)	13	1	240	3,120
45 CFR 1355.33 (c) On-site Review (CFSR)	13	1	1,170	15,210
45 CFR 1355.35 (a) Program Improvement Plan (CFSR)	13	1	240	3,120
45 CFR 1355.38 (b) and (c) Corrective Action	1	1	780	780

Estimated Total Annual Burden Hours: 22,860

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 5, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–10703 Filed 5–7–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 8, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira__submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0014. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigational New Drug Regulations—OMB Control Number 0910–0014—Extension

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in the FDA regulations ''Investigational New Drug Application'' in part 312 (21 CFR part 312). Part 312 implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) (the act) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts. The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. Submissions are reviewed by medical officers and other agency scientific reviewers assigned responsibility for overseeing the specific study. The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements are dictated by the scientific procedures and human subject safeguards that must be followed in the clinical tests of investigational new drugs.

The IND information collection requirements provide the means by which FDA can do the following: (1) Monitor the safety of ongoing clinical investigations; (2) determine whether the clinical testing of a drug should be authorized; (3) ensure production of reliable data on the metabolism and pharmacological action of the drug in humans; (4) obtain timely information on adverse reactions to the drug; (5) obtain information on side effects associated with increasing doses; (6) obtain information on the drug's effectiveness; (7) ensure the design of well-controlled, scientifically valid studies; (8) obtain other information pertinent to determining whether clinical testing should be continued and information related to the protection of human subjects. Without the information provided by industry in response to the IND regulations, FDA cannot authorize or monitor the clinical investigations which must be conducted prior to authorizing the sale and general use of new drugs. These reports enable FDA to monitor a study's progress, to assure subject safety, to assure that a study will be conducted ethically, and to increase the likelihood that the sponsor will conduct studies that will be useful in determining whether the drug should be marketed and available for use in medical practice.

There are two forms that are required under part 312:

Form FDA–1571—''Investigational New Drug Application.'' A person who intends to conduct a clinical investigation submits this form to FDA. It includes the following information: (1) A cover sheet containing background information on the sponsor and investigator, (2) a table of contents, (3) an introductory statement and general investigational plan, (4) an investigator's brochure describing the drug substance, (5) a protocol for each planned study, (6) chemistry, manufacturing, and control information for each investigation, (7) pharmacology and toxicology information for each investigation, and (8) previous human experience with the investigational drug.

The second form is Form FDA–1572—''Investigator Statement.'' Before permitting an investigator to begin participation in an investigation, the sponsor must obtain and record this form. It includes background information on the investigator and the investigation, and a general outline of the planned investigation and the study protocol.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements in part 312:

TABLE 1.—REPORTING AND RECORDKEEPING REQUIREMENTS IN 21 CFR PART 312

REPORTING REQUIREMENTS	
21 CFR Section	Requirements
.	
312.7(d)	Applications for permission to sell an investigational new drug
.	
312.8	Charging for investigational drugs under an IND
312.10	Applications for waiver of requirements under part 312; as indicated in § 312.10(a), estimates for this requirement are included under §§ 312.23 and 312.31. In addition, separate requests under § 312.10 are estimated in table 2 of this document.
.	
312.20(c)	Applications for investigations involving an exception from informed consent under § 50.24 (21 CFR 50.24); estimates for this requirement are included under § 312.23.
.	
312.23	INDs (content and format)
(a)(1)	Cover sheet FDA–1571
(a)(2)	Table of contents
(a)(3)	Investigational plan for each planned study
(a)(5)	Investigator's brochure
(a)(6)	Protocols—Phases 1, 2, and 3
(a)(7)	Chemistry, manufacturing, and control information
(a)(7)(iv)(*a*), (*b*), and (*c*)	A description of the drug substance, a list of all components, and any placebo used

TABLE 1.—REPORTING AND RECORDKEEPING REQUIREMENTS IN 21 CFR PART 312—Continued

REPORTING REQUIREMENTS	
21 CFR Section	Requirements
(a)(7)(iv)(*d*)	Labeling: Copies of labels and labeling to be provided each investigator
(a)(7)(iv)(*e*)	Environmental impact analysis regarding drug manufacturing and use
(a)(8)	Pharmacological and toxicology information
(a)(9)	Previous human experience with the investigational drug
(a)(10)	Additional information
(a)(11)	Relevant information
(f)	Identification of exception from informed consent
.	
312.30	Protocol amendments
(a)	New protocol
(b)	Change in protocol
(c)	New investigator
(d)	Content and format
(e)	Frequency
.	
312.31	Information amendments
(b)	Content and format Chemistry, toxicology, or technical information
.	
312.32	Safety reports
(c)(1)	Written reports to FDA and to investigators
(c)(2)	Telephone reports to FDA for fatal or life-threatening experience
(c)(3)	Format or frequency
(d)	Followup submissions
.	
312.33	Annual reports
(a)	Individual study information
(b)	Summary information
(b)(1)	Adverse experiences
(b)(2)	Safety report summary
(b)(3)	List of fatalities and causes of death
(b)(4)	List of discontinuing subjects
(b)(5)	Drug action
(b)(6)	Preclinical studies and findings
(b)(7)	Significant changes
(c)	Next year general investigational plan
(d)	Brochure revision
(e)	Phase I protocol modifications
(f)	Foreign marketing developments
.	
312.35	Treatment use of investigational new drugs
(a)	Treatment protocol submitted by IND sponsor
(b)	Treatment IND submitted by licensed practitioner
.	
312.36	Requests for emergency use of an investigational new drug
.	
312.38(b) and (c)	Notification of withdrawal of an IND
.	
312.42(e)	Sponsor requests that a clinical hold be removed and submits a complete response to the issues identified in the clinical hold order
.	
312.44(c) and (d)	Opportunity for sponsor response to FDA when IND is terminated
.	
312.45(a) and (b)	Sponsor request for, or response to, inactive status determination of an IND
.	
312.47(b)	''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings
.	
312.53(c)	Investigator information; investigator report (Form FDA–1572) and narrative; investigator's background information; Phase 1 outline of planned investigation; and Phase 2 outline of study protocol
.	
312.54(a) and (b)	Sponsor submissions concerning investigations involving an exception from informed consent under § 50.24
.	
312.55(b)	Sponsor reports to investigators on new observations, especially adverse reactions and safe use; only ''new observations'' are estimated under this section; investigator brochures are included under § 312.23
.	
312.56(b), (c), and (d)	Sponsor monitoring of all clinical investigations, investigators, and drug safety; notification to FDA
.	
312.58(a)	Sponsor's submission of records to FDA on request
.	
312.64	Investigator reports to the sponsor

TABLE 1.—REPORTING AND RECORDKEEPING REQUIREMENTS IN 21 CFR PART 312—Continued

REPORTING REQUIREMENTS	
21 CFR Section	Requirements
(a)	Progress reports
(b)	Safety reports
(c)	Final reports
312.66	Investigator reports to Institutional Review Board; estimates for this requirement are included under § 312.53
312.70(a)	Investigator disqualification; opportunity to respond to FDA
312.83	Sponsor submission of treatment protocol; estimates for this requirement are included under §§ 312.34 and 312.35
312.85	Sponsors conducting Phase 4 studies; estimates for this requirement are included under § 312.23 in 0910–0014, and §§ 314.50, 314.70, and 314.81 in 0910–0001
312.110(b)	Request to export an investigational drug
312.120	Submissions related to foreign clinical studies not conducted under an IND
312.130(d)	Request for disclosable information for investigations involving an exception from informed consent under § 50.24
RECORDKEEPING REQUIREMENTS	
21 CFR Section	Requirements
312.52(a)	Transfer of obligations to a contract research organization
312.57	Sponsor recordkeeping
312.59	Sponsor recordkeeping of disposition of unused supply of drugs; estimates for this requirement are included under § 312.57
312.62(a)	Investigator recordkeeping of disposition of drugs
312.62(b)	Investigator recordkeeping of case histories of individuals
312.120(d)	Recordkeeping requirements for submissions related to foreign clinical studies not conducted under an IND; estimates for this requirement are included under § 312.57
312.160(a)(3)	Records maintenance: shipment of drugs for investigational use in laboratory research animals or in vitro tests
312.160(c)	Shipper records of alternative disposition of unused drugs

In the **Federal Register** of February 11, 2009 (74 FR 6889), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

In tables 2 and 3 of this document, the estimates for ''No. of Respondents,'' ''No. of Responses per Respondent,'' and ''Total Annual Responses'' were obtained from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) reports and data management systems for submissions received in 2007 and from other sources familiar with the number of submissions received under 21 CFR part 312. The estimates for ''Hours per Response'' were made by CDER and CBER individuals familiar with the burden associated with these reports and from estimates received from the pharmaceutical industry.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS AND BIOLOGICS (CDER)[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.7(d)	28	1.58	44	24	1,056
312.10	4	1	4	10	40
312.23(a) through (f)	2,496	1.26	3,156	1,600	5,049,600
312.30(a) through (e)	2,030	8.91	18,079	284	5,134,436

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS AND BIOLOGICS (CDER)[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.31(b)	153	2.97	454	100	45,400
312.32(c) and (d)	985	23.06	22,713	32	726,816
312.33(a) through (f)	2,564	2.34	5,994	360	2,157,840
312.35(a) and (b)	9	1.11	10	300	3,000
312.36	525	1.23	645	16	10,320
312.38(b) and (c)	654	1.34	874	28	24,472
312.42(e)	149	1.10	164	284	46,576
312.44(c) and (d)	159	1.13	179	16	2,864
312.45(a) and (b)	254	1.43	362	12	4,344
312.47(b)	281	1.8	529	160	84,640
312.53(c)	900	26.51	23,855	80	1,908,400
312.54(a) and (b)	1	1	1	48	48
312.55(b)	985	2,306	2,271,300	48	109,022,400
312.56(b) ,(c), and (d)	18	1	18	80	1,440
312.58(a)	91	4.10	373	8	2,984
312.64	141,393	1	141,393	24	3,393,432
312.70(a)	4	1.5	6	40	240
312.110(b)	23	18.26	420	75	31,500
312.120[2]	115	5	575	32	18,400
312.130(d)	3	1	3	8	24

[1] There are no capital and startup, or operation, maintenance, and purchase costs associated with the collection of information requirements.
[2] Section 312.120 includes the burden estimate for both CDER and CBER.

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS AND BIOLOGICS (CDER)[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
312.52(a)	683	1	683	2	1,366
312.57	75	485.28	36,396	100	3,639,600
312.62(a)	14,732	1	14,732	40	589,280
312.62(b)	147,320	1	147,320	40	5,892,800
312.160(a)(3)	547	1.4	782	.5	391
312.160(c)	547	1.4	782	.5	391

[1] There are no capital and startup, or operation, maintenance, and purchase costs associated with the collection of information requirements.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS (CBER)[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Responses	Total Hours
312.7(d)	12	1.1	13	24	312
312.23(a) through (f)[2]	168	1.5	256	1,600	409,600
312.30(a) through (e)	372	6.4	2,369	284	672,796

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS (CBER)[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Responses	Total Hours
312.31(b)[2]	703	7.7	5,417	100	541,700
312.32(c) and (d)	175	14.6	2,563	32	82,016
312.33(a) through (f)	512	2.3	1,168	360	420,480
312.35(a) and (b)	1	1	1	300	300
312.36	10	4	40	16	640
312.38(b) and (c)	81	1.5	120	28	3,360
312.42(e)	74	1.5	108	284	30,672
312.44(c) and (d)	34	1.1	39	16	624
312.45(a) and (b)	41	1.4	59	12	708
312.47(b)	31	1.2	37	160	5,920
312.53(c)	243	4.95	1,203	80	96,240
312.54(a) and (b)	1	1	1	48	48
312.55(b)	42	1	43	48	2,064
312.56(b), (c), and (d)	10	1.6	16	80	1,280
312.58(a)	7	1	7	8	56
312.64	2,728	3.82	10,411	24	249,864
312.70(a)	5	1	5	40	200
312.110(b)	18	1	18	75	1,350
312.130(d)	1	1	1	8	8

[1] There are no capital and startup, or operation, maintenance, and purchase costs associated with the collection of information requirements.
[2] The reporting requirement for § 312.10 is included in the estimates for §§ 312.23 and 312.31.

TABLE 5.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS (CBER)[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
312.52(a)	52	1.4	73	2	146
312.57	168	3.05	512	100	51,200
312.62(a)	2,560	1	2,560	40	102,400
312.62(b)	2,560	10	25,600	40	1,024,000
312.160(a)(3)	55	1.4	77	0.5	38.5
312.160(c)	55	1.4	77	0.5	38.5

[1] There are no capital and startup, or operation, maintenance, and purchase costs associated with the collection of information requirements.

TABLE 6.—TOTALS FOR ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS FOR CDER AND CBER

Reporting Burden	130,190,510
Recordkeeping	11,301,652
Total	141,492,162

Dated: May 1, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10730 Filed 5–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0048] (formerly Docket No. 2007E–0445)

Determination of Regulatory Review Period for Purposes of Patent Extension; NEUPRO TRANSDERMAL SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NEUPRO TRANSDERMAL SYSTEM 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 human drug product 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 Director 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 NEUPRO TRANSDERMAL SYSTEM (rotigotine). NEUPRO TRANSDERMAL SYSTEM is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NEUPRO TRANSDERMAL SYSTEM (U.S. Patent No. 6,884,434) from Schwarz Pharma Limited, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 28, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NEUPRO TRANSDERMAL SYSTEM 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 NEUPRO TRANSDERMAL SYSTEM is 4,367 days. Of this time, 3,535 days occurred during the testing phase of the regulatory review period, while 832 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 (the act) (21 U.S.C. 355(i)) became effective*: May 27, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 27, 1995.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 28, 2005. The applicant claims January 19, 2005, as the date the new drug application (NDA) for NEUPRO TRANSDERMAL SYSTEM (NDA 21–829) was initially submitted. However, FDA records indicate that NDA 21–829 was initially submitted on January 28, 2005, the date of receipt by the Agency of a resubmission following a refusal to file.

3. *The date the application was approved*: May 9, 2007. FDA has verified the applicant's claim that NDA 21–829 was approved on May 9, 2007.

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, this applicant seeks 744 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 7, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 4, 2009. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.