Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Mentoring ToolKit Web-based Needs Assessment Questionannaire	442	1	.75	332
Mentoring ToolKit Web-based focus group	40	1	1	40
Mentoring ToolKit Web-based Feedback questionnaire	100	1	.25	25

Estimated Total Annual Burden Hours: 397

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 15, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–790 Filed 2–21–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0252]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEVEMIR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEVEMIR 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 that 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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 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 LEVEMIR (insulin determir (rDNA origin)). LEVEMIR is indicated for once or twice-daily subcutaneous administration in the treatment of adult patients with diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LEVEMIR (U.S. Patent No. 5,750,497) from Novo Nordisk A/S, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LEVEMIR represented the first permitted commercial marketing or use of the product. 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 LEVEMIR is 2,896 days. Of this time, 1,971 days occurred during the testing phase of the regulatory review period, while 925 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) became effective*: July 14, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 14, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 5, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for LEVIMIR (NDA 21–536) was initially submitted on December 5, 2002.

3. *The date the application was approved*: June 16, 2005. FDA has verified the applicant's claim that NDA 21–536 was approved on June 16, 2005.

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 1,496 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 April 23, 2007. 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 August 21, 2007. 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.

Dated: February 3, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–3001 Filed 2–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3271–EM]

Colorado; Amendment No. 3 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Colorado (FEMA–3271–EM), dated January 7, 2007, and related determinations.

EFFECTIVE DATE: February 12, 2007.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Colorado is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of January 7, 2007:

Cheyenne, Huerfano, and Kiowa Counties for emergency protective measures (Category B), including snow removal, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Under Secretary for Federal Emergency Management and Director of FEMA.

[FR Doc. E7–2948 Filed 2–21–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1680–DR]

Florida; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Florida (FEMA–1680–DR), dated February 8, 2007, and related determinations.

EFFECTIVE DATE: February 8, 2007.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated February 8, 2007, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Florida resulting from severe storms, tornadoes, and flooding on December 25, 2006, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Florida.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act you may deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs. If Public Assistance is later warranted, Federal funds provided under that program will also be limited to 75 percent of the total eligible costs. Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Director, under Executive Order 12148, as amended, Jesse Munoz, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Florida to have been affected adversely by this declared major disaster:

Volusia County for Individual Assistance.

All counties within the State of Florida are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program-Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Under Secretary for Federal Emergency Management and Director of FEMA.

[FR Doc. E7–2935 Filed 2–21–07; 8:45 am]

BILLING CODE 9110–10–P