FDA recently approved for marketing the medical device, FREESTYLE NAVIGATOR. FREESTYLE NAVIGATOR is indicated for continually recording interstitial fluid glucose levels in people (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FREESTYLE NAVIGATOR (U.S. Patent No. 5,262,035) from Abbott Diabetes Care Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of FREESTYLE NAVIGATOR represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period. FDA has determined that the applicable regulatory review period for FREESTYLE NAVIGATOR is 2,320 days. Of this time, 750 days occurred during the testing phase of the regulatory review period, while 1,570 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date clinical investigation on humans is begun as approved by an institutional review board (IRB) under section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and when no investigational device exemption (IDE) is required:* November 6, 2001. The applicant claims that investigation of the device qualified for a non-significant risk study for the purpose of establishing clinical data necessary to support a subsequent premarket approval under section 515 of the FD&C Act. FDA has verified the applicant's claim that the device did not require an IDE under section 520(g) of the FD&C act, but did require IRB approval, granted November 6, 2001, for human tests to begin. This date represents the beginning of the testing phase of the regulatory review period.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 25, 2003. The applicant claims November 24, 2003, as the date the first premarket approval application (PMA) for FREESTYLE NAVIGATOR (PMA P030048) was initially submitted. However, FDA records indicate that PMA P030048 was submitted on November 25, 2003.

3. *The date the application was approved:* March 12, 2008. FDA has verified the applicant's claim that PMA P050020 was approved on March 12, 2008.

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 1,826 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**) either electronic or written comments and ask for a redetermination by February 14, 2011. 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 June 13, 2011. 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.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–31240 Filed 12–13–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–E–0037 and FDA–2010–E–0038]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SAMSCA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 (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 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 SAMSCA (tolvaptan). SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for SAMSCA (U.S. Patent Nos. 5,258,510 and 5,753,677) from Otsuka Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SAMSCA 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 SAMSCA is 4,722 days. Of this time, 4,147 days occurred during the testing phase of the regulatory review period, while 575 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* June 16, 1996. The applicant claims October 23, 1997, as the date the investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for tolvaptan was June 16, 1996, which was 30 days after FDA receipt of this first IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 23, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for SAMSCA (NDA 22–275) was submitted on October 23, 2007.

3. *The date the application was approved:* May 19, 2009. FDA has verified the applicant's claim that NDA 22–275 was approved on May 19, 2009.

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 applications for patent extension, this applicant seeks 1,826 days or 1,827 days respectively 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**) either electronic or written comments and ask for a redetermination by February 14, 2011. 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 June 13, 2011. 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.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–31298 Filed 12–13–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; GuLF Worker Study: Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 7 October 2010 on pages 62132–3 and allowed 60-days for public comment. One public comment was received and addressed regarding the appropriateness and sources for funding the survey. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

5 CFR 1320.5: Reporting and Recordkeeping Requirements: Final Rule: Respondents to this collection of information are not required to respond unless the data collection instruments display a currently valid OMB control number.

Proposed Collection

Title: GuLF Worker Study: Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of the GuLF Study is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures surrounding the Deepwater Horizon disaster; and to create a resource for additional collaborative research on focused hypotheses or subgroups. Over 55,000 persons participating in oil-spill clean-up activities have been exposed to a range of known and suspected toxins in crude oil, burning oil, and dispersants, to excessive heat, and possibly to stress due to widespread economic and lifestyle disruption. Exposures range from negligible to potentially significant, however, potential long-term human health