ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Average burden hours per response	Response burden (in hours)
Form D: CBA Training Events Report	32 CBA Provider Grantees	12	2	768
Total				1952

Dated: May 18, 2007.

Maryam Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–10031 Filed 5–23–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0457]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), 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 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 SOMAVERT (pegvisomant). SOMAVERT is indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SOMAVERT (U.S. Patent No. 5,849,535) from Genentech, 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 April 6, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SOMAVERT 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 SOMAVERT is 2,169 days. Of this time, 1,349 days occurred during the testing phase of the regulatory review period, while 820 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*: April 18, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 18, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 26, 2000. The applicant claims December 22, 2000, as the date the new drug application (NDA) for SOMAVERT (NDA 21–106) was initially submitted. However, FDA records indicate that NDA 21–106 was submitted on December 26, 2000.

3. *The date the application was approved*: March 25, 2003. FDA has verified the applicant's claim that NDA 21–106 was approved on March 25, 2003.

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 466 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 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 November 20, 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: May 7, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–10052 Filed 5–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT933–07–4310–DP]

Notice of Intent To Prepare Supplemental Draft Resource Management Plans and Environmental Impact Statements for the Vernal and Price Field Offices, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the Bureau of Land Management (BLM), Vernal and Price Field Offices, Utah, are preparing Supplemental Draft Resource Management Plans/Environmental Impact Statements (Draft RMP/EIS) to include additional information and analyses of wilderness characteristics on lands outside existing Wilderness Study Areas (WSAs). This information and analysis includes multiple areas in both the Vernal and Price Field Office planning areas.

DATES: Because the BLM has previously requested (**Federal Register**, Volume 66, Number 48, March 12, 2001, pages 14415–14417, and **Federal Register**, Volume 66, No. 216, November 7, 2001, pages 56343–56344) and received extensive information from the public on issues to be addressed in these RMPs, and because the Council on Environmental Quality (CEQ) regulations for implementing the National Environmental Policy Act (NEPA) do not require additional scoping for this supplemental draft RMP/EIS process (40 CFR 1502.9(c)(4), the BLM is not asking for further public information and comment at this time. This issue has been defined in earlier scoping efforts. A 90-day public comment period will be provided upon release of the supplemental draft document EISs.

FOR FURTHER INFORMATION CONTACT: Shelley Smith, Project Manager, BLM Utah State Office, P.O. Box 45155, Salt Lake City, Utah 84145–0155; telephone: (801) 539–4053; e-mail: *shelley_smith@blm.gov*. The public may also contact Howard Cleavinger, Assistant Field Manager, BLM Vernal Field Office, 170 South 500 East, Vernal, Utah 84078; telephone: (435) 781–4480; e-mail: *howard_cleavinger@blm.gov* or Floyd Johnson, Assistant Field Manager, BLM Price Field Office, 125 South 600 West, Price, Utah 84501; telephone: (435) 636–3650; e-mail: *floyd_johnson@blm.gov*. Or, the public may visit the Price RMP Web site at *http://www.blm.gov/rmp/ut/price* and the Vernal RMP Web site at *http://www.blm.gov/rmp/ut/vernal.*

SUPPLEMENTARY INFORMATION: There are multiple areas in the Price and Vernal Field Offices, outside of existing wilderness study areas (WSAs), found to have wilderness characteristics in previous inventories. The BLM's Land Use Planning Handbook (H–1601–1) provides guidance for consideration of non-WSA lands with wilderness characteristics in land use planning. The handbook provides that the BLM consider these lands and resource values in planning, and prescribe measures to protect wilderness characteristics. These characteristics include appearance of naturalness, outstanding opportunities for solitude, or outstanding opportunities for primitive and unconfined recreation.

To ensure compliance with the ruling in the court case, *Southern Utah Wilderness Alliance et al.* v. *Gale Norton,* in her official capacity as Secretary of the Interior *et al.* (Utah District Court, Case No. 2:04CV574DAK), regarding the sale and issuance of oil and gas leases on lands outside of existing WSAs with wilderness characteristics, the BLM is supplementing its consideration of non-WSA lands with wilderness characteristics in land use planning. BLM shall ensure that (1) adequate consideration is given to wilderness characteristics in ongoing RMPs, (2) a range of alternatives is analyzed for management of these lands, and (3) an adequate analysis is prepared from which to base decisions for future oil and gas leasing.

Dated: April 4, 2007.

Jeff Rawson,

Associate State Director.

[FR Doc. E7–10032 Filed 5–23–07; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Bernice Pauahi Bishop Museum, Honolulu, HI; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of a revision to an inventory of human remains in the possession of the Bernice Pauahi Bishop Museum (Bishop Museum), Honolulu, HI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects information reported in a Notice of Inventory Completion for the Bishop Museum published in the **Federal Register** on August 27, 1997 (FR Doc 97–22736, pages 45437–45438). Officials of the Bishop Museum have determined that 24 of the 34 cultural items published in the original notice do not meet the definition of human remains at 43 CFR 10.2 (d)(1) because while these items contain human remains, the items themselves are not considered human remains under NAGPRA definitions. The 24 cultural items that are being removed from the inventory are listed below.

In 1889, Joseph S. Emerson sold a wood image from Waimea, O'ahu, to the Bishop Museum. Human hair is incorporated in this object. No known individual was identified.

In 1889, a helmet (or wig) incorporating human hair and a refuse container incorporating human teeth and bone were bequeathed to the Bishop Museum by Queen Emma. No known individual was identified.

In 1889, a kahili incorporating human bone became part of the original collections of the Bishop Museum. This kahili was given to Bernice Pauahi by Ke'elikolani. No known individual was identified.

In 1891, a refuse container incorporating human teeth and a kahili incorporating human bone were acquired with the collections of the Hawaiian National Museum which were