0001). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. The burden totals do not include an increase in burden. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					4,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–6095 Filed 3–13–02; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1672]

Ashford Blood Bank, Inc.; Revocation of U.S. License No. 0740–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 0740–001) issued to Ashford Blood Bank, Inc., for the manufacture of Whole Blood and Red Blood Cells. Ashford Blood Bank, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its license.

DATES: The revocation of the biologics license (U.S. License No. 0740–001) is effective March 14, 2002.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is revoking the biologics license (U.S. License No. 0740–001) issued to Ashford Blood Bank, Inc., Ashford Medical Center, suite 401–402, Santurce, PR 00907, for the manufacture of Whole Blood and Red Blood Cells. FDA initiated proceedings to revoke the biologics license because: (1) Authorized FDA employees were unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility as mandated under § 600.21 (21 CFR 600.21), and (2) manufacturing of products had been discontinued to an extent that a meaningful inspection or evaluation could not be made. In a certified, return-receipt letter dated October 28, 1997, FDA notified an authorized official of the firm that FDA had suspended the establishment's biologics license for the manufacture of Whole Blood and Red Blood Cells at its facilities at Santurce, PR, and Bayamon, PR. This action was based on the fact that significant deviations from the regulations were noted by FDA's San Juan district office during inspections of the facilities conducted August 19, 1997, through September 17, 1997, and September 9, 1997, through September 17, 1997, respectively. FDA's San Juan district office attempted to conduct additional inspections of the two Ashford facilities. On May 1, 1998, FDA investigators attempted to inspect the satellite collection facility at Bayamon, PR, but found that the facility was no longer in operation, and the manufacturing of Whole Blood and Red Blood Cells had been discontinued. On November 23, 1999, FDA investigators attempted to inspect the main facility in Santurce, PR, but found that the facility was no longer in operation and the manufacturing of Whole Blood and Red Blood Cells had been discontinued.

In certified, return-receipt letters dated April 13, 2000, sent to the establishment's facility at Santurce, PR, and also to the Ashford Blood Bank, Inc., P.O. Box 195034, San Juan, PR, 00919, FDA notified an authorized official of the firm that FDA's attempt to conduct inspections of the two facilities at Santurce, PR and Bayamon, PR were unsuccessful because the facilities were no longer in operation and the manufacture of Whole Blood and Red Blood Cells had been discontinued. The letter advised the establishment that, under § 601.5(b)(l) and (b)(2) (21 CFR 601.5(b)(1) and (b)(2)) (now codified as § 601.5(b)(1)(i) and (b)(1)(ii)), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection required under § 600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection could not be made at the establishment, FDA may initiate proceedings for license revocation. FDA also stated that a meaningful inspection could not be made at the establishment's facilities and issued to the establishment a notice of FDA's intent to revoke U.S. License No. 0740–001 and announced its intent to offer an opportunity for a hearing.

Under § 12.21(b) (21 CFR 12.21(b)), FDA published in the **Federal Register** of February 6, 2001 (66 FR 9087), a notice of opportunity for a hearing on a proposal to revoke the biologics license of Ashford Blood Bank, Inc. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the establishment because it was no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The notice provided the establishment 30 days to submit a written request for a hearing and 60 days to submit any data and information

justifying a hearing. The notice provided other interested persons with 60 days to submit written comments on the proposed revocation. The establishment did not respond within the 30-day time period with a written request for a hearing, and under § 12.21(b), the 30-day time period prescribed in the notice of opportunity for a hearing may not be extended. No other comments were received.

Accordingly, under 21 CFR 12.38, section 351 of the Public Health Service Act (42 U.S.C. 262), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), the biologics license (U.S. License No. 0740–001) issued to Ashford Blood Bank, Inc., is revoked, effective March 14, 2002.

Dated: March 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–6096 Filed 3–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

DEPARTMENT OF AGRICULTURE

Forest Service

[CA 668–02–1610–DO–083A]

Monument Advisory Committee Meeting Schedule

AGENCY: Bureau of Land Management, Interior; United States Forest Service, Agriculture.

ACTION: Notice of meetings.

SUMMARY: The Bureau of Land Management (BLM) and United States Forest Service (USFS) announces the schedule of meetings for the Advisory Committee to the Santa Rosa and San Jacinto Mountains National Monument (hereinafter referred to as ''National Monument''). The meetings will be held on the following dates:

Saturday, April 6, 2002
Saturday, June 1, 2002
Saturday, August 3, 2002
Saturday, October 5, 2002
Saturday, December 7, 2002
Saturday, February 1, 2003

The meetings will be held at the Palm Desert City Hall Council Chambers, located at 73–510 Fred Waring Drive, Palm Desert, California, 92260. The meetings will take place from 9 a.m. until 4:00 p.m. There will be a half hour dedicated to public input during both the first half hour of the meetings and at the last half hour of the meetings. A sign up sheet will be located at the meeting room on the day of the meeting. Speakers wishing to comment publicly should sign the public comment sign-in sheet provided at the location of the meetings and provide a written copy of their statement. All committee and subcommittee meetings, including field examinations, will be open to the general public, including representatives of the news media. Any organization, association, or individual may file a statement with or appear before the committee and its subcommittees regarding topics on a meeting agenda—except that the chairperson or the designated federal official may require written comments to the Advisory Committee. The meetings will have agendas developed and available to the public prior to the meeting date. The agendas for each meeting will be located on the Bureau of Land Management web page for the Santa Rosa San Jacinto National Monument (*http://www.ca.blm.gov/palmsprings/.*) The subject matter of each meeting will focus on the development and implementation of the Santa Rosa San Jacinto Mountains National Monument Management Plan.

The Monument Advisory Committee (MAC) is a committee of citizens appointed to provide advice to the BLM and USFS with respect to preparation and implementation of the management plan for the National Monument as required in the Santa Rosa and San Jacinto Mountains National Monument Act of 2000 (16 U.S.C. 431nt). The act authorized establishment of the MAC with representative members from State and local jurisdictions, the Agua Caliente Band of Cahuilla Indians, a natural science expert, local conservation organization, local developer or building organization, the Winter Park Authority and a representative from the Pinyon Community Council.

The meetings will be open to the public with attendance limited to space available. Individuals who plan to attend and need special assistance such as sign language interpretations or other reasonable accommodations should notify the contact person listed below in advance of the meeting. Persons wishing to make statements will need to sign up at the meeting location.

DATES: April 6, 2002; June 1, 2002; August 3, 2002; October 5, 2002; December 7; 2002; February 1, 2003; All meetings will take place from 9 a.m. to 4 p.m with a morning public comment period from 9 to 9:30 a.m. and an afternoon public comment period from 3:30 to 4 p.m.

ADDRESSES: The meetings will be held in the Council Chambers of the Palm Desert City Hall, 73–510 Fred Waring Drive, Palm Desert, California, 92260.

FOR FURTHER INFORMATION CONTACT: Written comments should be sent to Miss Danella George, Santa Rosa San Jacinto Mountains National Monument Manager, Bureau of Land Management, P.O. Box 581260, North Palm Springs, CA 92258; or by fax at (760) 251–4899 or by e-mail at *dgeorge@ca.blm.gov.* Information can be found on our webpage: *http://www.ca.blm.gov/palmsprings/.* Documents pertinent to this notice, including comments with the names and addresses of respondents, will be available for public review at the Palm Springs-South Coast Field Office located at 690 W. Garnet Avenue, North Palm Springs, California, during regular business hours 8 a.m. to 4:30 p.m., Monday through Friday, except holidays.

SUPPLEMENTARY INFORMATION: The Santa Rosa and San Jacinto Mountains National Monument was established by act of Congress and signed into law on October 24, 2000. The National Monument was established in order to preserve the nationally significant biological, cultural, recreational, geological, educational and scientific values found in the Santa Rosa and San Jacinto Mountains. This legislation established the first monument to be jointly managed by the Bureau of Land Management (BLM) and the U.S. Forest Service (USFS). The Santa Rosa and San Jacinto Mountains National Monument Act of 2000 affects only Federal lands and Federal interests located within the established boundaries.

The 272,000 acre Monument encompasses 86,400 acres of Bureau of Land Management lands, 64,400 acres of Forest Service lands, 23,000 acres of Agua Caliente Band of Cahuilla Indians lands, 8,500 acres of California Department of Parks and Recreation lands, 35,800 acres of other State of California agencies lands, and 53,900 acres of private land. The BLM and the Forest Service will jointly manage Federal lands in the National Monument in coordination with the Agua Caliente Band of Cahuilla Indians, other federal agencies, state agencies and local governments.