

What other considerations should be taken into account in connection with such a conversion?

3. What other steps must your organization take in order to be prepared to smoothly transition into a role as administrator of a new temporary reinsurance program?

4. Does your organization operate nationally or in limited geographic areas? If the latter, what are the geographic areas?

5. Would your organization be able and willing to contract with a State and/or the Federal government to operate a temporary reinsurance program?

6. Are there any State and/or local licensing requirements that must be considered by an organization operating as such a reinsurance entity?

7. What potential conflicts of interest (COIs) could arise if your organization were to operate such a reinsurance program as a not-for-profit entity? How might these COIs be mitigated?

8. For organizations that do not currently have COI mitigation programs, what steps would have to be taken to develop and execute such a program?

9. What is a reasonable amount of time for your organization to become fully operational (for example, have all systems in place to operate a reinsurance program) after the date of a contract award? What resources would be necessary?

Collection and Disbursement of Reinsurance Funds

10. Describe your organization's ability to perform the following functions:

- Collecting reinsurance contributions;
- Accepting and validating requests for reinsurance payments;
- Remitting reinsurance payments; and,
- Reconciling and verifying reinsurance contributions and payments.

11. What services related to the collection of reinsurance contributions, or disbursement of reinsurance payments to another entity would your organization need to subcontract due to a lack of capacity, expertise, or experience?

12. What COIs could arise for such potential subcontractors?

Data Collection

13. Describe current data systems that are used by your organization, including any standards, security systems, and web-based interactive structure. Are your systems compliant or have the capability of being Section 508

compliant (<http://www.section508.gov/>)?

14. Do your organization's current data systems have the capability to interface with external systems to accept data and reports? If yes, what types of interfaces are currently in place?

15. What data are currently collected by your organization related to medical costs?

16. What is your organization's current capacity for collecting and verifying claims submissions from issuers? What processes does your organization have in place to ensure confidentiality and security protections of patient information?

17. In what formats does your organization currently collect data? Can your organization support other formats? If so, which ones?

18. Would your organization need to subcontract any services related to data collection?

19. What COIs could arise for such subcontractors?

Customer Support

20. What telecommunication and technical support systems does your organization currently maintain for health insurance issuers or other commercial clients (for example, Web sites, 24-hour hotlines, helpdesk)?

21. Are your support systems compliant or have the capability of being Section 508 compliant (<http://www.section508.gov/>)?

22. Would your organization need to subcontract any services related to data collection?

23. What COIs could arise for such subcontractors?

Evaluation

24. Does your organization currently conduct evaluations of operations and activities? Do such evaluations include a financial assessment of your organization's activities?

25. What are your organization's current financial and data reconciliation processes?

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: January 20, 2012.

Charles Littleton,

Contracting Officer, Office of Acquisition and Grants Management, Centers for Medicare and Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 23, 2012, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, (301) 796-9001, Fax: (301) 847-8533, email: PADAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application 202450, for aclidinium bromide, sponsored by Forest Laboratories, for the proposed

indication of long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 8, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 31, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 1, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 24, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: Date and Time: The meeting will be held on February 29, 2012, from 8:30 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877, (301) 977-8900. For those unable to attend in person, the meeting will also be Web cast. The Blood Products Advisory Committee Web cast will be available at <http://fda.yorkcast.com/webcast/Viewer/?peid=11253ea88a9041e5a91883236f342bfc1d>.

Contact Person: Bryan Emery or Pearl Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, (301) 827-1281, or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC area, and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and

call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 29, 2012, the committee will discuss the evaluation of possible new plasma products manufactured following storage at room temperature for up to 24 hours, namely, plasma for transfusion prepared from whole blood held at room temperature for up to 24 hours prior to separation and freezing, or from apheresis plasma held at room temperature for up to 24 hours before freezing. In the afternoon, the committee will hear the following updates: Report from the Health and Human Services Advisory Committee on Blood Safety and Availability and summary of the December 5-6, 2011, meeting; update on HHS activities related to the evaluation of the donor deferral policy for men who have had sex with other men; summary of the November 8-9, 2011, public workshop on hemoglobin standard and maintaining an adequate blood supply; summary of the November 29, 2011, public workshop on data and data needs to advance risk assessment for emerging infectious diseases for blood and blood products; and an update on thrombotic adverse events and immune globulin products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 21, 2012. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:45 p.m. on February 29, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2012. Time allotted for each presentation may be