§ 640.74 Modification of Source Plasma.

(a) Upon approval by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, of a supplement to the biologics license application for Source Plasma, a manufacturer may prepare Source Plasma as a liquid product for a licensed blood derivative manufacturer who has indicated a need for a liquid product.

(b) * * *

(2) * * * Such evidence may be submitted by either the licensed manufacturer of the Source Plasma Liquid or the manufacturer of the final blood derivative product who has requested the Source Plasma Liquid.

* * * * *

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

62. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

63. Section 660.21 is amended by revising paragraphs (a)(3) and (d) to read as follows:

§ 660.21 Processing.

(a) * * *

(3) A lot may be subdivided into clean, sterile vessels. Each subdivision shall constitute a sublot. If lots are to be subdivided, the manufacturer shall include this information in the biologics license application. The manufacturer shall describe the test specifications to verify that each sublot is identical to other sublots of the lot.

* * * * *

(d) *Volume of final product.* Each manufacturer shall identify the possible final container volumes in the biologics license application.

* * * * *

64. Section 660.30 is amended by revising paragraph (b) to read as follows:

§ 660.30 Reagent Red Blood Cells.

* * * * *

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32 of this chapter, or from umbilical cord cells which shall be collected and prepared according to the manufacturer's biologics license application.

65. Section 660.33 is amended by revising the fifth sentence to read as follows:

§ 660.33 Testing of source material.

* * * Where fewer than three donor sources of an antibody specificity are available, test discrepancies shall be resolved in accordance with the manufacturer's biologics license application. * * *

Dated: August 30, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–27159 Filed 10–19–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

Environmental Impact Considerations

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 1 to 99, revised as of Apr. 1, 1999, page 240, § 25.32 is corrected by reinstating text missing from the end of paragraph (i) and the beginning of paragraph (j). In the eighth line of paragraph (i) ''percdditive'' is corrected to read ''percent additive'' and the following text is added between the words ''percent'' and ''additive'':

§ 25.32 Foods, food additives, and color additives.

* * * * *

(i) * * * –by–weight and is expected to remain with finished food–packaging material through use by consumers or when the substance is a component of a coating of a finished food–packaging material.

(j) Approval of a food * * *

* * * * *

[FR Doc. 99–55537 Filed 10–19–99; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 202 and 206

RIN 1010–AB57

Training Sessions on Gas Valuation for Indian Leases

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of training sessions.

SUMMARY: The Minerals Management Service is offering six training sessions on our revised Indian gas valuation regulations that are effective January 1, 2000.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for meeting addresses.

FOR FURTHER INFORMATION CONTACT: Ms. Vicki Skinner, Royalty Valuation Division, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3152, Denver, CO 80225–0165; telephone number (303) 275–7241, fax number (303) 275–7227.

SUPPLEMENTARY INFORMATION: The dates and locations of the training sessions are as follows:

1. *Oklahoma City, OK:* November 1, 1999, 9 a.m. to 4 p.m., Central time. Clarion Airport West Hotel, 737 S. Meridian, Oklahoma City, OK 73108; telephone number (405) 942–8511.

2. *Tulsa, OK:* November 3, 1999, 9 a.m. to 4 p.m., Central time. Radisson Inn, 2201 N. 77th East Ave., Tulsa, OK 74115; telephone number (918) 835–9911.

3. *Farmington, NM:* November 16, 1999, 9 a.m. to 4 p.m., Mountain time. Holiday Inn, 600 E. Broadway, Farmington, NM 87401; telephone number (505) 327–9811.

4. *Houston, TX:* November 30, 1999, 9 a.m. to 4 p.m., Central time. Embassy Suites Hotel, 9090 Southwest Freeway, Houston, TX 77074; telephone number (713) 995–0123.

5. *Dallas, TX:* December 6, 1999, 9 a.m. to 4 p.m., Central time. Embassy Suites Market, 2727 Stemmons Freeway, Dallas, TX 75207; telephone number (214) 630–5332.

6. *Denver, CO:* December 15, 1999, 9 a.m. to 4 p.m., Mountain time. Holiday Inn, 14707 W. Colfax Ave., Golden, CO 80401; telephone number (303) 279–7611.

MMS published revised Indian gas valuation regulations in the **Federal Register** on August 10, 1999 (64 FR 43506). The revised regulations add alternative valuation methods to existing regulations to ensure that Indian lessors receive maximum revenues from their mineral resources as required by the unique terms of Indian leases and MMS's trust responsibility to Indian lessors. The revised regulations will also improve the accuracy of royalty payments at the time royalties are due.

If you produce gas from Indian lands, the new regulations affect you, and we strongly encourage you to attend one of these training sessions. Some of the topics that will be covered include: