thereafter until the required divestiture is completed.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute interpretation of the agreement and proposed Order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 97–33439 Filed 12–22–97; 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION

Federal Acquisition Policy Division, FAR Secretariat Revision of Standard Forms

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The General Services Administration/FAR Secretariat has revised SF 1423, Inventory Verification Survey, SF 1426, Inventory Schedule A-Metals in Mill Product Form; SF 1428, Inventory Schedule B; SF 1430, Inventory Schedule C—(Work-In-Process); SF 1432, Inventory Schedule D—(Special Tooling and Special Test Equipment); SF 1434, Termination Inventory Schedule E (Short Form for Use With SF 1438 Only) to remove the need for particular certification requirements, and update the burden statement.

Since these forms are authorized for local reproduction, you can obtain new camera copy in three ways:

On the U.S. Government Management Policy CD–ROM;

On the internet. Address: http://www.gsa.gov/forms, or;

From CARM, Attn.: Barbara Williams, (202) 501–0581.

FOR FURTHER INFORMATION CONTACT:

FAR Secretariat, (202) 501–4755. This contact is for information on completing the form and interpreting the FAR only.

DATES: Effective December 23, 1997.

Dated: December 16, 1997.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 97–33472 Filed 12–22–97; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section; NIOSH Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Safety and Occupational Health Study Section, National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5:30 p.m., February 12, 1998. 8 a.m.–5:30 p.m., February 13, 1998.

Place: Old Town Alexandria Holiday Inn, 480 King Street, Alexandria, Virginia, 22314.

Status: Open business session, 8 a.m.–8:30 a.m., February 12, 1998; Closed evaluation sessions 8:30 a.m.–5:30 p.m., February 12, 1998; and 8 a.m.–5:30 p.m., February 13, 1998.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas. It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be discussed: The meeting will convene in open session from 8 a.m.–8:30 a.m. on February 12, 1998, to address matters related to the conduct of Study Section business. The meeting will proceed in closed session from 8:30 a.m. until scheduled adjournment (5:30 p.m.) on February 12, 1998. The meeting will continue in closed session from 8 a.m. until scheduled adjournment (5:30 p.m.) or earlier on February 13, 1998. The purpose of the closed sessions is for the Safety and Occupational Health Study Section to consider safety and occupational health related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552(c) (4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: December 17, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–33412 Filed 12–22–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0510]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for manufacturers of medicated animal feeds.

DATES: Submit written comments on the collection of information by February 23, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practice Regulations for Medicated Feeds—(21 CFR Part 225)—(OMB Control Number 0910–0152—Reinstatement)

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (CGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for CGMP's have been codified under part 225 (21 CFR 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to ensure that proper quality control is maintained. Such records would, e.g., contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds, to investigate violative drug residues in products from treated animals, and to investigate product defects when a drug is recalled. In addition, FDA will use the CGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to ensure that their feeds meet the requirements of the act as to safety and also meet their claimed identity, strength, quality, and purity as required by section 501(a)(2)(B) of the act.

A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs which FDA has determined requires more control because of the need for a withdrawal period before slaughter or carcinogenic concerns. Conversely, for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control, a license is not required and the recordkeeping requirements are less demanding. Respondents to this collection of information are commercial feed mills and mixer-feeders.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)[1] [2]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	1,600	24	38,400	0.41	16,000
225.58(c) and (d)	1,600	24	38,400	0.25	9,600
225.80(b)(2)	1,600	24	38,400	0.16	6,400
225.102(b)(1) through (b)(5)	1,600	24	38,400	1.0	38,400
225.110(b)(1) and (b)(2)	1,600	24	38,400	0.25	9,600
225.115(b)(1) and (b)(2)	1,600	24	38,400	0.25	9,600
Total					89,600

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)[1] [2]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	200	3	600	0.16	100
225.58(c) and (d)	200	3	600	0.16	100
225.80(b)(2)	200	3	600	0.083	50
225.102(b)(1) through (b)(5)	200	3	600	0.5	300
225.110(b)(1) and (b)(2)				[3]	
225.115(b)(1) and (b)(2)				[3]	
Total					550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Mixer-feeders.
[3] There is no burden because medicated feeds are consumed on site (225.110 Distribution Records; 225.115—Complaint files).

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED)[1] [2]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	13,000	24	316,800	0.41	132,000
225.158	13,000	24	316,800	0.25	79,200
225.180	13,000	24	316,800	0.16	52,800
225.202	13,000	24	316,800	1.5	475,200
Total					739,200

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

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED)[1] [2]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	45,000	3	135,000	0.16	22,500
225.158	45,000	3	135,000	0.16	22,500
225.180	45,000	3	135,000	0.083	11,250
225.202	45,000	3	135,800	0.5	67,500
Total					123,750

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

The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to finally calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from agency records and experience.

Dated: December 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33487 Filed 12–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0376]

Plascon, Inc., dba Anderson Plasma Center; Denial of Request for a Hearing and Revocation of U.S. License No. 572–003

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying the request for a hearing and revokes the establishment license (U.S. license number 572–003) and product license issued to Plascon, Inc., doing business as Anderson Plasma Center, for the manufacture of Source Plasma. The agency finds that there is no genuine and substantial issue of fact justifying a hearing on the revocation of Plascon's licenses. The licenses are revoked due to the firm's failure to comply with the applicable biologics regulations and license standards designed to ensure the safety, purity, and potency of the manufactured products.

DATES: The revocation of the establishment license (U.S. License No. 572–003) and product license is effective December 23, 1998.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 17, 1995 (60 FR 57719), FDA announced an opportunity for a hearing on its proposal to revoke the establishment license (U.S. License No. 572–003) and product license issued to Plascon, Inc., doing business as Anderson Plasma Center, for the manufacture of Source Plasma (60 FR 57719). By letter dated December 12, 1995, Plascon requested a hearing on the proposed revocation. The agency is denying the request for a hearing and is revoking U.S. License No. 572–003, which includes the establishment license and product license, because the agency finds there is no genuine and substantial issue of fact regarding the basis for the proposed revocation for the firm's failure to comply with applicable Federal regulations and license standards. FDA has documented Plascon's failure to conform to such standards during inspections of Plascon in 1989, 1991, 1992, and 1993.

During a December 1989 inspection of Plascon, FDA investigators documented numerous deviations from the current good manufacturing practice (CGMP) regulations. The deviations included, but were not limited to, the following: (1) Failure to adequately determine donor suitability (part 606 (21 CFR part 606)) (§ 606.100(b)(1)) and (part 640 (21 CFR part 640)) (§ 640.63(c)); (2) failure to maintain accurate donor records (§ 606.160(b)(1)); (3) failure to ensure that personnel were competent in the performance of their duties (§ 606.20(b)); and (4) poor record keeping practices related to quality control, equipment calibration, and maintenance (§ 606.160(b)(5) and (b)(7)).

An FDA inspection of Plascon in September 1991 revealed similar CGMP deficiencies, as well as additional violations, including: (1) Failure to follow the standard operating procedures (SOP's) for documenting donor weight loss of 10 or more pounds or referring these donors to the physician on call (§ 606.100); (2) failure to record donor blood losses (§ 606.160(b)); (3) failure to maintain adequate facilities (§ 606.40); and (4) failure to properly maintain equipment (§ 606.60).

During an inspection of Plascon from August through October 1992, FDA inspectors found CGMP deviations similar to those documented during the