TABLE 2--Registrants Requesting Voluntary Cancellation—Continued

EPA Company no.	Company Name and Address
000352 .	E. I. Du Pont De Nemours & Co, Inc., Barley Mill Plaza, Walker's Mill, Wilmington, DE 19880.
000655 .	Prentiss Inc., 21 Vernon Street, C.B. 2000, Floral Park, NY 11001.
002393 .	Haco, Inc., Box 7190, Madison, WI 53707.
002935 .	Wilbur Ellis Co., 191 W. Shaw Ave, Fresno, CA 93704.
003125 .	Bayer Corp., Agriculture Division, 8400 Hawthorn Rd., Box 4913, Kansas City, MO 64120.
007056 .	IQ Products Co, Attn: Marty York, 16212 State Hwy 249, Houston, TX 77086.
010182 .	Zeneca Ag Products, Box 15458, Wilmington, DE 19850.
050534 .	ISK Biosciences Corp., 5966 Heisley Rd., Box 8000, Mentor, OH 44061.

III. Procedures for withdrawal of request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before February 15, 1996. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for one year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in Federal Register No. 123, Vol. 56, dated June 26, 1991. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide productswhich are currently in the United States and which have beenpackaged, labeled, and released for shipment prior to the effectivedate of the cancellation action. Unless the provisions of anearlier order apply, existing stocks already in the hands ofdealers or users can be distributed, sold or used legally untilthey are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pest, Product registrations.

Dated: November 3, 1995.

Frank Sanders,

Director, Program Management & Support Division, Office of Pesticide Programs.

[FR Doc. 95–28392 Filed 11–16–95; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0376]

Plascon, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 572–003

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 572–003) and the product license issued to Plascon, Inc., doing business as Anderson Plasma Center, for the manufacture of Source Plasma. The proposed revocation is based on the firm's history of continued noncompliance with the applicable biologics regulations and the license standards.

DATES: The firm may submit a written request for a hearing to the Dockets Management Branch by December 18, 1995, and any data and information justifying a hearing by January 16, 1996. Other interested persons may submit written comments on the proposed revocation by January 16, 1996.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA is proposing to revoke the establishment license (U.S. License No. 572–003) and the product license issued to Plascon, Inc., doing business as Anderson Plasma Center, 2507 Nichol Ave., Anderson, IN 46011, for the manufacture of Source Plasma.

During preapproval and routine inspections conducted by FDA at Plascon, Inc., in 1989, 1991, 1992, and 1993, significant deviations from the applicable Federal regulations and the license standards were documented. Following each of these inspections, FDA provided to Plascon, Inc., written documentation of the deviations observed; FDA then requested that Plascon, Inc., indicate in writing what corrective action plan would be undertaken to remedy the deviations. Following the 1992 inspection, FDA issued a warning letter dated November 12, 1992, to Plascon, Inc., advising the firm that failure to promptly correct the deviations observed during the inspection could result in regulatory action by FDA without further notice.

In response to FDA's inspectional observations, in letters dated December 19, 1989, October 17, 1991, and January 6, 1993, Plascon, Inc., proposed corrective action plans. However, subsequent inspections of Plascon, Inc., by FDA continued to demonstrate that sufficient and effective long-term corrective action had not been achieved. Plascon, Inc.'s, cumulative inspectional history thus established a pattern of continued noncompliance with the applicable Federal regulations and license standards.

The most recent inspection, conducted from December 13 through December 17, 1993, revealed continuing significant deviations from the applicable regulations and the license standards. These deviations included, but were not limited to, the following: (1) Failure to adequately determine donor suitability (21 CFR 606.100(b)(1)

and 640.63(c)); (2) failure to investigate donor adverse reactions (21 CFR 606.170(a)); (3) failure to perform adequate donor physical examinations (21 CFR 640.63(b)(3) and 640.63(c)(9)); (4) failure to provide suitable facilities (21 CFR 606.40(a)(1)); (5) failure to perform and maintain records of quality control for equipment and reagents (21 CFR 606.60(a), 606.160(b)(5)(i), and 606.160(b)(7)(iv)); and (6) failure to maintain complete and accurate records and follow standard operating procedures (21 CFR 606.160(b)(1)(i), 606.160(b)(1)(ii), and 640.65(b)(3)).

Accordingly, due to the serious nature of the deviations, which the Commissioner of Food and Drugs determined to constitute a danger to health, FDA suspended the firm's licenses by letter dated January 11, 1994. In a letter to FDA dated January 20, 1994, Plascon, Inc., requested that revocation be held in abeyance and that a time extension be granted by which another corrective action plan would be submitted. By letter dated January 27, 1994, FDA granted the request for a time extension to submit in writing the corrective action plan. By letter dated January 28, 1994, Plascon, Inc., requested a second time extension for submission of the plan. By letter dated, February 10, 1994, FDA granted the second time extension. By letter dated February 21, 1994, Plascon, Inc., submitted the corrective action plan to FDA.

After consideration of Plascon, Inc.'s, submission, FDA sent a letter dated May 5, 1994, denying Plascon, Inc.'s, request that the license revocation be held in abeyance. FDA advised Plascon, Inc., that the most recent corrective action plan was incomplete and inadequate, and that Plascon, Inc.'s, claim that sufficient corrective actions would be implemented and sustained was not credible in light of the firm's careless disregard of the applicable regulations and standards. In accordance with § 601.5(b) (21 CFR 601.5(b)), FDA advised Plascon, Inc., that no additional time would be provided in which to demonstrate compliance with the regulations and standards before FDA would initiate proceedings to revoke Plascon, Inc.'s, licenses. Plascon, Inc., was offered the option of voluntarily requesting that the licenses be revoked. Plascon, Inc., was further advised that, should that option not be exercised, FDA would initiate proceedings to revoke the license by publishing in the Federal Register a notice of opportunity for a hearing on a proposal to revoke the licenses, pursuant to § 12.21(b) (21 CFR 12.21(b)), as provided in § 601.5(b). Plascon, Inc., did not respond to FDA's letter within the specified response period.

Thus, under § 12.21(b), FDA is issuing a notice of opportunity for a hearing on a proposal to revoke Plascon, Inc.'s, licenses. FDA has placed copies of letters between FDA and Plascon, Inc., concerned with the revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) November 12, 1992, warning letter from FDA to Plascon, Inc.; (2) January 6, 1993, response letter from Plascon, Inc., to FDA regarding FDA inspectional findings of inspection conducted between August 11, 1992, and October 21, 1992; (3) January 7, 1994, response letter from Plascon, Inc., to FDA regarding FDA inspectional findings of inspection conducted between December 13, 1993, and December 17, 1993; (4) January 11, 1994, letter from FDA to Plascon, Inc., suspending the firm's licenses; (5) January 20, 1994, letter from Plascon, Inc., to FDA requesting that license revocation be held in abeyance and that an extension of time be granted to submit another corrective action plan; (6) January 27, 1994, letter from FDA granting the request for an extension of time to submit in writing a corrective action plan; (7) January 28, 1994, letter from Plascon, Inc., requesting a second extension of time for submission of a corrective action plan; (8) February 10, 1994, letter from FDA to Plascon, Inc., granting the second extension of time; (9) February 21, 1994, letter from Plascon, Inc., submitting a corrective action plan to FDA; and (10) May 5, 1994, letter from FDA to Plascon, Inc., denying the firm's request that the revocation be held in abeyance and advising Plascon, Inc., that the corrective action plan submitted by letter dated February 21, 1994, was incomplete and inadequate and that FDA would institute license revocation proceedings. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Plascon, Inc., may submit a written request for a hearing to the Dockets Management Branch by December 18, 1995, and any data and information justifying a hearing must be submitted by Janaury 16, 1996. Other interested persons may submit comments on the proposed revocation by January 16, 1996.

FDA procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on a proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is not genuine and substantial issue of fact for resolution at a hearing, or if a request for a hearing is not made within the specified time, or in the required format or the required analyses, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act (sec. 351 (42 U.S.C. 262)) and the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 505, 701 (21 U.S.C. 321, 351, 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: November 8, 1995.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 95–28367 Filed 11–16–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.