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

previous two inspections, despite Plascon's assurances that the firm was in compliance with Federal regulations. The violations observed during this inspection included: (1) Failure to adequately investigate donor adverse reactions (§§ 606.170(a), 606.100(b)(9), and 606.160(b)(1)(iii)); (2) failure to maintain complete and accurate records of donors (§ 606.160(b)(1)); (3) failure to maintain the plasma at a proper storage temperature (§§ 606.100(b)(10) and 640.76(a)(1)); (4) failure to adequately observe, standardize, or calibrate equipment (§§ 606.100(b)(15) and 606.60); (5) failure to maintain adequate facilities (§ 606.40); and (6) failure to follow SOP's (§ 606.100). FDA issued a warning letter to Plascon on November 12, 1992. In the warning letter, FDA stated that Plascon was responsible for ensuring that operations at all of its centers were in full compliance with the Federal Food, Drug, and Cosmetic Act (the act), 21 U.S.C. 301 *et seq.*, and its implementing regulations, and requested that Plascon take prompt action to correct the deviations noted. The warning letter notified Plascon that failure to take prompt corrective action could result in regulatory action without further notice, including license suspension and/or revocation. On January 6, 1993, Plascon sent a letter to FDA promising corrective action.

FDA conducted another inspection of Plascon in July 1993 and documented continued deficiencies, including: (1) Failure to adequately determine donor suitability (§§ 606.100(b)(1) and 640.63(c)); (2) failure to maintain adequate facilities (§ 606.40); and (3) failure to provide adequate equipment maintenance (§ 606.60).

At the conclusion of each of these inspections, FDA issued to Plascon a list of observations from the inspection (Form FDA–483), which detailed Plascon's continuing noncompliance with the applicable regulations and license standards. After each inspection, Plascon promised corrective action.

Subsequently, FDA conducted an inspection of Plascon on December 11 through December 17, 1993, and FDA again documented numerous CGMP deviations. The CGMP violations observed included the following, among others: (1) Failure to adequately determine donor suitability (§§ 606.100(b)(1) and 640.63(c)); (2) failure to investigate adverse donor reactions (§ 606.170(a)); (3) failure to perform adequate physical examinations on donors (§ 640.63(b) and (c)); (4) failure to perform and maintain records of quality control for equipment and reagents (§§ 606.60(a), 606.160(b)(5) and (b)(7)); and (5) failure to maintain complete and accurate records and to follow SOP's (§§ 606.160(b) and 640.65(b)(3)).

Due to the serious nature of the deviations from the applicable regulations and the standards in Plascon's licenses, which the agency determined to constitute a danger to health, on January 11, 1994, FDA suspended Plascon's licenses and denied the firm's pending license supplements for automated collection of Source Plasma. FDA's suspension letter noted that the basis for the suspension was Plascon's serious noncompliance with donor protection standards that are designed to assure a continuous and healthy donor population, and the firm's noncompliance with standards designed to assure the continued safety, purity, potency, and quality of the manufactured products. (Letter from FDA to Plascon, January 11, 1994, at p. 4.) The suspension letter stated that ''[t]he nature of the deficiencies * * * leads us to conclude that they are a direct consequence of [Plascon's] disregard for the applicable regulations and standards in [Plascon's] license application.'' (*Id.*) The suspension letter notified Plascon that its licenses were suspended and that FDA would proceed to revoke Plascon's licenses unless the firm requested that revocation be held in abeyance pending resolution of the matters involved and provided FDA with a written description of the ''specific actions taken to correct all deficiencies noted'' in the suspension letter.

By letter dated January 20, 1994, Plascon requested that FDA hold the proposed revocation of its licenses in abeyance and extend until January 31, 1994, the time for Plascon to prepare and submit a corrective action plan. On January 27, 1994, FDA granted the request for a time extension to submit the corrective action plan. By letter dated January 28, 1994, Plascon requested that FDA extend until February 21, 1994, the time for Plascon to submit a corrective action plan. On February 10, 1994, FDA granted the second-time extension request. By letter dated February 21, 1994, Plascon submitted its corrective action plan to FDA.

After considering Plascon's corrective action plan, FDA, by letter dated May 5, 1994, denied the firm's request that the license revocation be held in abeyance. FDA explained that the

''current and previous inspections of [Plascon] have revealed continuing significant deviations from applicable regulations and standards specified in [Plascon's] license and establish[] a pattern of failure to implement appropriate and lasting corrections of these deviations.''

(Letter from FDA to Plascon dated May 5, 1994, at p. 1.) FDA advised Plascon that its corrective action plan was incomplete and inadequate and detailed some of the plan's inadequacies. In addition, FDA explained that the ''nature of the deficiencies and continued noncompliance * * * demonstrates careless disregard for the applicable regulations and the standards of [Plascon's] license.'' (*Id.* at p. 2.) FDA's letter notified Plascon that ''[i]n cases involving willfulness, the agency need not provide an opportunity for the licensee to demonstrate or achieve compliance,'' and that FDA was ''initiating proceedings to revoke'' Plascon's licenses. (*Id.*)

Subsequently, in the **Federal Register** of November 17, 1995, FDA announced a notice of opportunity for a hearing (NOOH) on the proposed revocation of the establishment license and product license issued to Plascon. In the NOOH, FDA advised Plascon that 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 (60 FR 57719 at 57720). The NOOH further stated that if it appeared conclusively from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there was no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs (the Commissioner) would deny the hearing request (60 FR 57719 at 57720).

In a letter dated December 12, 1995, Plascon requested a hearing on the proposed license revocation. On January 12, 1996, Plascon submitted ''data and information'' in support of its request. (See § 12.24 (21 CFR 12.24).) In its letter, Plascon stated that the firm ''does not deny that during a series of inspections between 1989 and 1993 by FDA inspectors, a variety of deviations from the applicable federal regulations were observed.'' (Letter from Plascon to FDA, January 12, 1996, at p. 1–2.) However, Plascon argued that FDA's determination that Plascon's continued operation posed a danger to health was not supported by an adequate factual basis. Plascon argued that a ''reasonable and valid connection must be established between the deviations noted [by FDA] and the 'danger to health' alleged.'' (*Id.* at p. 1.) Plascon further argued that a hearing was necessary so that the ''largely unsupported conclusion of a public health danger can be set forth, explored, and tested during the course of a hearing.'' (*Id.*)

Plascon's letter of January 12, 1996, also referred to and enclosed a letter that Plascon sent to FDA on June 29, 1994, regarding the disposition of inventory of Source Plasma on hand at Plascon when FDA suspended Plascon's licenses. In its June 29, 1994, letter, the firm stated that it did not seek to ''justify or minimize the deviations from regulatory requirements that were observed during the various FDA inspections'' (letter from Plascon to FDA, June 29, 1994, at p. 2), and conceded that the conditions at Plascon's facilities during the December 1993 inspection were ''deplorable.'' (*Id.* at p. 3.) Nevertheless, Plascon argued that ''the safety, purity, potency, and quality of much of the Source Plasma collected during that time period can indeed be assured.'' (*Id.* at p. 2.)

II. Applicable Regulations

In accordance to § 601.6 (21 CFR 601.6), whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist, and that by reason thereof there is a danger to health, he may notify the licensee that his license is suspended (§ 601.6(a).) Upon suspension of a license, the Commissioner shall either: (1) Proceed in accordance to the provisions of § 601.5(b) (21 CFR 601.5(b)) to revoke the license; or (2) if the licensee agrees, hold revocation in abeyance pending resolution of the matters involved (§ 601.6(b).)

The grounds for revocation are set forth at § 601.5(b). In accordance to § 601.5(b)(4), if the Commissioner finds that the establishment or the product for which a license has been issued fails to conform to the applicable standards established in the license and the regulations designed to ensure the continued safety, purity, and potency of the manufactured product, he shall notify the licensee of his intention to revoke the license, setting forth the grounds for, and offering an opportunity for a hearing on, the proposed revocation. Except as provided in § 601.6 or in cases involving willfulness, the notification of intent to revoke shall provide a reasonable period for the licensee to demonstrate or achieve compliance with the applicable requirements before proceedings will be instituted for revocation of the license (§ 601.5(b).)

The procedures for hearings on the revocation of biologics licenses are set forth in part 12 (21 CFR part 12). (See § 601.7.) The criteria for deciding whether to grant or deny a hearing are stated in § 12.24(b). These regulations provide that 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 (§ 12.24(b)(1)(2).) If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that requires a hearing on the revocation of the license, the Commissioner will deny the hearing request and enter summary judgment against the licensee. (§ 12.24(b)(1); see also *Costle* v. *Pacific Legal Found.*, 445 U.S. 198, 214–15 (1980); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–21 (1973).) Moreover, where the issues raised in the hearing request are, even if true, legally insufficient to alter the decision, the Commissioner need not grant a hearing. (§ 12.24(b)(4) (hearing request will not be granted ''if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought'').) Therefore, to warrant a hearing, Plascon must set forth a genuine and substantial issue of fact concerning the grounds for revocation of its licenses.

III. Plascon's Hearing Request and the Commissioner's Findings

Plascon's challenge to the proposed revocation of its establishment and product licenses is a narrow one. Plascon's hearing request and the data and information the firm submitted in support of its hearing request do not challenge whether Plascon failed to comply with applicable regulations and the standards set forth in the firm's licenses; instead, Plascon only disputes whether Plascon's deviations from FDA's regulations constitute a ''danger to health.'' (See, e.g., Letter from Plascon to FDA, January 12, 1996, p. 3 (''The fact that there were deviations from regulatory requirements * * * does not automatically establish that a 'danger to health' was present. Danger to who? The employees? The donors? * * * These are factual issues that require exploration at the requested hearing * * *'').) For the reasons set forth below, the agency finds that there is no genuine and substantial issue of fact justifying a hearing and therefore denies Plascon's request for a hearing.

Before proceeding to the basis for Plascon's request for a hearing, the agency notes that FDA's decision to initiate revocation proceedings without providing Plascon with a further opportunity to demonstrate or achieve compliance was appropriate. As noted above, FDA's regulations provide:

> Except as provided in [21 CFR] 601.6 or in cases involving willfulness, the notification [of intent to revoke] shall provide a reasonable period for the licensee to demonstrate or achieve compliance with the requirements of this chapter, before proceedings will be instituted for revocation of the license.

(§ 601.5(b).)

After FDA suspended Plascon's licenses in January 1994, in response to Plascon's request, FDA held revocation of the firm's licenses in abeyance pending resolution of the matters involved. (See § 601.6(b).) FDA's January 11, 1994, suspension letter notified Plascon that FDA would proceed with revocation unless, *inter alia*, the firm notified FDA in writing of the:

> specific actions taken to correct all deficiencies noted in this letter including a detailed explanation of all retraining of all personnel as well as the means by which such training is to be evaluated.

(Letter from FDA to Plascon, January 11, 1994, at p. 6.)

FDA granted both of the extensions that Plascon requested for submission of a corrective action plan. Subsequently, after considering Plascon's February 21, 1994, submission, FDA advised Plascon by letter that the firm's corrective action plan was incomplete and inadequate and that the firm'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 this letter, FDA also notified Plascon that it no longer would hold the license revocation in abeyance and that the agency would initiate revocation proceedings. (Letter from FDA to Plascon, May 5, 1994, at p. 2.) Citing the May 5, 1994, letter, the November 17, 1995, NOOH also noted Plascon's ''careless disregard of the applicable regulations and standards'' and stated that FDA had advised Plascon ''that no additional time would be provided in which to demonstrate compliance'' before FDA would initiate revocation proceedings (60 FR 57710 at 57720).

The agency notes that Plascon's hearing request and the data and information it submitted in accordance to that request do not challenge the May 5, 1994, letter's assertion that Plascon had acted in careless disregard of the applicable regulations and standards. Similarly, the firm has not objected to FDA's decision to institute revocation proceedings without providing Plascon further opportunity to demonstrate or achieve compliance. (Letter from Plascon to FDA, December 12, 1995; Letter from Plascon to FDA, January 12, 1996.)

While the Commissioner does not need to reach the issue of whether FDA's decision not to provide further opportunity to demonstrate or achieve compliance was proper under § 601.5, he notes that § 601.5 requirements have been satisfied because Plascon's conduct was willful within the meaning of § 601.5. Courts that have considered the meaning of willfulness in the context of license revocation proceedings have noted that willful conduct can be found when a person acts with careless disregard of statutory requirements. (See, e.g., *Potato Sales Co., Inc.* v. *United States Dept. of Agric.*, 92 F.3d 800, 805 (9th Cir. 1996); *Cox* v. *United States Dept. of Agric.*, 925 F.2d 1102, 1105 (8th Cir. 1991), *cert. denied*, 502 U.S. 860 (1991); *Lawrence* v. *Commodity Futures Trading Corp.*, 759 F.2d 767, 773 (9th Cir. 1985); *Finer Food Sales Co.* v. *Block*, 708 F.2d 774, 778 (D.C. Cir. 1983); *American Fruit Purveyors Inc.* v. *United States*, 630 F.2d 370, 374 (5th Cir. 1980), *cert. denied*, 450 U.S. 997 (1981).) Plascon's pattern of continued noncompliance with the applicable license standards and regulations, despite ample notice from the FDA of the firm's noncompliance and repeated assurances from Plascon that the firm would come into compliance, demonstrates careless disregard of the applicable requirements. Thus, the agency finds that Plascon's conduct was willful within the meaning of § 601.5, and thus it was not necessary to provide Plascon with further opportunity to demonstrate or achieve compliance.

The next issue for consideration is whether the data and information Plascon submitted raise a genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1).) FDA's proposed revocation of Plascon's establishment and product licenses is based on Plascon's failure to adhere to the applicable regulations and the standards in Plascon's license application, not on a finding that these failures constitute a ''danger to health.'' (Letter from FDA to Plascon, May 5, 1994, at p. 1–3; 60 FR 57719.) FDA's focus on Plascon's failure to comply with the applicable regulations and standards conforms to the applicable regulations. (See § 601.5(b)(4).)

The grounds for revocation set forth in § 601.5(b)(4) have been established in this case. As described above, FDA's inspections documented Plascon's deviations from the applicable regulations and standards during four inspections between 1989 and 1993. Plascon has not only failed to submit any data and information challenging FDA's inspectional findings, but also has admitted that the firm failed to comply with the applicable regulations. Indeed, by the firm's own characterization, the conditions observed during the 1993 inspection, which led to the suspension and proposed revocation of Plascon's licenses, were ''deplorable.'' (See Letter from Plascon to FDA, June 29, 1994, at p. 3 (''[I]t is a source of great regret'' that the:

> conditions observed by FDA investigators * * * during the[] December 13–17, 1993 inspection of [Plascon] were so deplorable, resulting in the issuance of a Form FDA–483 with 66 inspectional observations * * * [T]he facility was not operating in an acceptable manner, and [Plascon] accepts full responsibility for that extremely unfortunate situation.);

see also *id.* at p. 2 (''Without for a moment seeking to justify or minimize the deviations from regulatory requirements that were observed during the various FDA inspections over the more than four year period of time * * *''); *id.* at p. 25 (''The final inspection, in December of 1993, was by far the 'worst' of these inspections * * *''); *id.* at 28 (''*if* the December 1993 inspection had been a completely successful one, instead of the disaster that it obviously was * * *''); Letter from Plascon to FDA dated February 21, 1994, Corrective Action Plan, at p. 2 (''Plascon, Inc. has terminated employees who were not following proper protocol during the most recent FDA inspection.'').)

Having conceded the existence of the ''deplorable'' conditions at Plascon, the firm confines its challenge to the proposed revocation of its licenses to whether FDA established the existence of a danger to health when the agency suspended Plascon's licenses on May 5, 1994. More specifically, Plascon argues that the regulatory deficiencies observed did not affect the quality of the Source Plasma manufactured by the firm and that FDA has not established the existence of a ''danger to health.'' (Letter from Plascon to FDA dated January 12, 1996, at p. 1.) However, while the issue of whether the Commissioner had reasonable grounds to believe that by reason of the existence of the grounds for revocation of Plascon's licenses there was ''a danger to health'' was relevant to the decision to *suspend* the firm's licenses, it has no bearing on the *revocation* of those licenses under § 601.5(b).

Plascon's hearing request will be granted only if the material submitted shows that there is a genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1)). A hearing will not be granted on factual issues that are not determinative with respect to the action requested (§ 12.24(b)(4)). As the District of Columbia Circuit Court of Appeals observed, ''Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.'' *Copanos & Sons* v. *FDA*, 854 F.2d 510, 523 (D.C. Cir. 1988). Plascon's hearing request raises only an irrelevant factual dispute, the resolution of which, even if in Plascon's favor, would have no bearing on the merits of the revocation of its licenses.

For the reasons set forth above, the agency finds that Plascon, Inc., doing business as Anderson Plasma Center, has failed to show that there is a genuine and substantial issue of fact justifying a hearing on the revocation of its establishment and product licenses. The agency also finds that significant deviations from the biologics regulations and the standards set forth in the firm's licenses existed which warrant revocation of Plascon's licenses. Therefore, under section 351 of the Public Health Service Act (42 U.S.C. 262) and under §§ 12.28, 601.5, and 601.7, the Commissioner denies the request for a hearing and revokes the establishment (U.S. License No. 572–003) and product licenses issued to Plascon, Inc., doing business as Anderson Plasma Center, for the manufacture of Source Plasma.

Dated: December 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33373 Filed 12–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Program Announcement Number FDA–CFSAN–98–1 Cooperative Agreement for Validation of Analytical Methods, Standards, and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), is announcing its intention to accept and consider a single source application for award of a cooperative agreement to support AOAC International in the amount of $100,000. The cooperative agreement will provide support for the Validation of Analytical Methods, Standards, and Procedures.