containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the Commission Actions section of the FTC Home Page (for September 3, 1997), on the World Wide Web, at ''http://www.ftc.gov/os/actions/htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent London International Group, Inc. (''London International'') a New Jersey corporation.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

London International manufactures and markets various brands of condoms to the public, including Ramses brand condoms. The Commission's complaint charges that respondent's advertising contained unsubstantiated comparative strength representations. Specifically, the complaint alleges that the respondent did not possess adequate substantiation for claims that: (1) Ramses brand condoms are thirty percent stronger than the leading brand; and (2) Ramses brand condoms break thirty percent less often than the leading brand.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent from engaging in similar acts and practices in the future.

Part I of the proposed order would prohibit the respondent from making any claim about: (1) The comparative or quantifiable strength of any condom; (2) the comparative or quantifiable risk of breakage of any condom; or (3) the comparative or quantifiable efficacy of any condom, unless at the time of making the claim, it possesses and relies upon competent and reliable evidence.

Part I contains a provision that would permit respondent to make any claim about condoms that is approved by the Food and Drug Administration (''FDA'') without violating the settlement. This provision, however, excludes claims that the FDA has permitted through clearing a ''premarket notification report,'' unless the clearance was based on a review and evaluation of the substantiation submitted with the report.

The proposed order also requires the respondent to maintain materials relied upon to substantiate claims covered by the order; to provide a copy of the consent agreement to all employees or representatives involved in the preparation and placement of the company's advertisements, as well as to all company executives and marketing and sales managers; to notify the Commission of any changes in corporate structure that might affect compliance with the order; and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 97–23979 Filed 9–9–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0391]

Central Georgia Plasma Lab, Inc.; Revocation of U.S. License No. 0649–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 0649–001) and product license issued to Central Georgia Plasma Lab, Inc. (Central Georgia), for the manufacture of Source Plasma. A notice of opportunity for a hearing on a proposal to revoke the licenses was published in the **Federal Register** of May 20, 1994 (59 FR 26503). Central Georgia subsequently requested a hearing. However, in a letter dated July 12, 1996, the firm notified FDA that it had ceased operations effective June 25, 1996, and voluntarily requested revocation of its licenses. The request for an opportunity for a hearing on the issue of license revocation became moot. FDA, therefore, proceeded to revoke the firm's licenses.

DATES: The revocation of the establishment license (U.S. License No. 0649–001) and product license became effective August 21, 1996.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA has revoked the establishment license (U.S. License No. 0649–001), which includes the product license issued to Central Georgia Plasma Lab, Inc., 652 Third St., Macon, GA 31201, for the manufacture of Source Plasma.

By letter dated May 27, 1993, FDA notified Central Georgia that it was instituting proceedings to revoke U.S. License No. 0649–001, and announced its intent to issue a notice of opportunity for a hearing. Central Georgia responded in a letter of June 1, 1993, and advised FDA that the firm did not wish to waive its opportunity for a hearing. In the **Federal Register** of May 20, 1994 (59 FR 26503), FDA announced an opportunity for a hearing on the proposal to revoke the establishment and product license issued to Central Georgia. In the notice of opportunity for a hearing, FDA described its finding that Central Georgia had willfully not complied with the applicable standards and regulations. As described in the notice of opportunity for a hearing, the grounds for the proposed license revocation included the following: (1) The results of FDA's inspections of the firm, beginning in 1981, but most recently from July 1989 through February 1993; (2) a determination by FDA that the deviations documented during the inspections of the firm demonstrated significant noncompliance with the applicable regulations and the standards and conditions established in the firm's licenses; (3) a determination that the nature of the deficiencies noted demonstrated the continuing failure of the Responsible Head to exercise control of the establishment in all matters relating to compliance and to assure that personnel are adequately trained and properly supervised and have a thorough understanding of the procedures that they perform, as required by 21 CFR 600.10(a) and 606.20(a). Documentation in support of the proposed revocation had been placed on file for public examination with the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Following publication of the notice of opportunity for a hearing and in accordance with the procedures set forth in parts 12 and 601 (21 CFR parts 12 and 601), on June 15, 1994, the Responsible Head of Central Georgia submitted a request for a hearing to the Dockets Management Branch and, on July 15, 1994, provided additional supplemental information to justify the request for a hearing.

While the request for a hearing was pending, the owner and former Responsible Head of Central Georgia informed the agency by letter dated July 12, 1996, that Central Georgia had closed its facility on June 24, 1996, and ceased operations effective June 25, 1996, and was voluntarily surrendering both the establishment and product licenses. FDA notified Central Georgia by letter of August 21, 1996, that the licenses had been revoked.

Based on the voluntary surrender of U.S. License No. 0649–001, Central Georgia's request for a hearing on the issue of license revocation became moot. Central Georgia effectively waived an opportunity for a hearing on the matter (§ 601.5(a)).

Accordingly, under § 601.5(a), section 351 of the Public Health Service Act (42 U.S.C. 262), 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 5.68), the establishment license (U.S. License No. 0649–001) and the product license issued to Central Georgia Plasma Lab, Inc., for the manufacture of Source Plasma were revoked, effective August 21, 1996.

This notice is issued and published under § 601.8 and the redelegation at 21 CFR 5.67.

Dated: August 25, 1997.

Mark Elengold,

Acting Deputy Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–23946 Filed 9-9-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: AIDS Drug Assistance Program [ADAP]: Monthly Client Utilization and Program Expenditure Assessment Project—NEW—State AIDS Drug Assistance Programs [ADAP], funded under section 2611 of the Public Health Service Act (commonly known as Title II of the Ryan White Comprehensive AIDS Resources Emergency [CARE] Act) are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medications that prevent serious deterioration of health arising from HIV disease, including prevention and treatment of opportunistic diseases.

Due to the increasing need for pharmaceuticals among uninsured and underinsured low-income individuals who are HIV+ or diagnosed with AIDS, and recognizing the importance of program planning and budget forecasting to maximize resources, the Division of Service Systems [DSS], Health Resources and Services Administration [HRSA], proposes to collect relevant client utilization data and program expenditure information on a voluntary monthly reporting basis from State ADAPs. This effort is designed to assist Title II grantees, State ADAPs, the DSS/HRSA funding agency staff, and policymakers at both the Federal and State level to better understand the level of client need for medications that the programs are functioning under and the resources used to meet the needs, and to provide indicators of where future action may be required and the most appropriate response(s).

A report is proposed that will collect monthly data on the level of expenditures and client utilization of services. In addition, the report will provide a forum for tracking the most current changes in each State ADAP with respect to available funding, eligibility criteria, clinical guidelines, and formulary changes. On a quarterly basis, the report will also request the prices of eight specified pharmaceuticals dispensed by each program. The individual State reports will be compiled into summary reports and distributed back to grantees and State ADAPs on a monthly basis, and will be available for use by HRSA and the Office of Management and Budget. These results will be used to guide program planning, to formulate budget recommendations, and to monitor the balance between available resources and State needs. The burden estimates are as follows:

Type of form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
ADAP Monthly Update	54	12	1	648
ADAP Quarterly Drug Pricing Update	54	4	1	216
Total	54	16	1	864