Pneumococcal infections cause invasive disease (commonly known as ''pneumonia''), meningitis and otitis media (commonly known as a ''middle ear infection''). Invasive disease may occur at any age, but is particularly dangerous in elderly patients. Meningitis is a dangerous result of pneumococcal infection and can occur in persons of all ages. Otitis media is common in children under age two. It is estimated that between 33 percent and 50 percent of all otitis media cases are caused by pneumococcal infections. Otitis media may resolve within three to four days without medical intervention, while more serious cases require a course of antibiotics. Approximately forty-seven million cases of otitis media require some form of medical intervention annually in the seven major markets for pharmaceutical products (U.S., France, Germany, Italy, Spain, U.K. and Japan).

CDC scientists have discovered a particular surface protein of pneumococcus designated pneumococcal surface adhesin A protein (''PsaA''). Their discoveries include the amino acid sequence and the polypeptide formed by said sequence. CLI is proposing that through incorporation of PsaA it will be able to produce a vaccine which is immunogenic in children without the requirement of a conjugated toxoid.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to Marjorie Hunter, Technology Licensing Specialist, Office of Technology Transfer, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–67, Atlanta, GA 30333, telephone: (404) 639–6271; facsimile: (404)639–6266. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: May 16, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–13426 Filed 5–21–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition; Notice of Intent to Establish a Cooperative Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single-source application for the award of a cooperative agreement to the University of Maryland at College Park (UMCP). The cooperative agreement will support the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and a new FDA laboratory/office building to be constructed in College Park, MD. JIFSAN is to be colocated on the UMCP campus. Competition is limited to UMCP because the Food and Drug Administration Revitalization Act directed FDA to consolidate the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM); and related congressional action directed the Centers to be located in Prince George's County, MD. The cooperative agreement is intended to create a partnership that allows for a more efficient use of research resources and thereby enhances the quality of food safety and nutrition research.

ADDRESSES: Applications may be obtained from, and should be submitted to, Robert L. Robins, Grants Management Officer, Office of Facilities, Acquisition and Central Services (HFA–520), Food and Drug Administration, Park Bldg., 5600 Fishers Lane, rm. 3–40, Rockville, MD 20857, 301–443–6170. Applications hand carried or commercially delivered should be submitted to Robert L. Robins, Park Bldg., 12420 Parklawn Dr., rm. 3–40, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice contact: Robert L. Robins (address above).

Regarding the programmatic aspects contact: Elizabeth M. Calvey, CFSAN (HFS–345), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–205–4716.

SUPPLEMENTAL INFORMATION:

I. Background

FDA is announcing its intention to accept and consider a single-source application from UMCP for a cooperative agreement to support the JIFSAN. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

UMCP's application for this award will undergo dual peer review. An ad hoc review panel of nonFederal experts (i.e., in areas associated with food safety, nutrition, and risk assessment) will review and evaluate the application based on its scientific merit. A second level review will be conducted by the National Advisory Environmental Health Sciences Council.

JIFSAN was established between FDA and the University of Maryland (the University) in April 1996 through a formal memorandum of understanding (MOU) to create a partnership that allows for more efficient use of research resources and thereby enhances the quality of food safety and nutrition research and public health policy. As the role of FDA research scientists in regulatory activities increases, it is vital that these scientists have ready access to very specialized research facilities and expertise (e.g., Center of Biomolecular Structure and Organization) in order to expedite regulatory policy and decisions (e.g., petition review). As described in the MOU of April 1996, JIFSAN is to be a jointly administered, multidisciplinary, research program. JIFSAN was established as part of FDA's consolidation project affecting CFSAN and CVM.

FDA's consolidation project was authorized through the Food and Drug Administration Revitalization Act (Pub. L. 101–635). The Treasury, Postal Service and General Government Appropriations Act, 1992 (Pub. L. 102–141) directed that new construction for the consolidation of FDA occur in Montgomery and Prince George's Counties, Maryland. The Congressional Conference Report (H. Rept. 102–234, 1991) related to this law further specifies that FDA begin consolidating its current programs into two campuses:

(1) A headquarters campus to include administrative and drug research facilities, in Montgomery County, and (2) a food and veterinary sciences campus in Prince George's County. To this end, the General Services Administration, through its site selection process, purchased land in the vicinity of the College Park metro rail station intended as the location for consolidation of CFSAN and CVM.

In the United States, there is no single center for research and development of expertise and analytical methodology in food safety and applied nutrition. In a January 1997 radio address, the President emphasized the need for Government, academia, industry, and consumers to work together to improve the safety of the food supply. FDA is in the vanguard of this effort, establishing the National Center for Food Safety and Technology (NCFST) with the Illinois Institute of Technology in 1988, and now, establishing JIFSAN with UMCP. The missions of NCFST and JIFSAN are mutually dependent. The focus of NCFST is food technology, specifically the effect of innovative food processing and packaging technologies on the safety of the food supply. The focus of JIFSAN is food safety and nutrition, specifically as related to risk analysis, applied microbiology, natural toxins, chemical contaminants, and an integrated program of study of food composition and nutrition.

II. Establishment of JIFSAN

A. Concept

FDA believes that the cooperative research program with UMCP to be established at JIFSAN will provide opportunities to leverage resources so that important national and international problems in food safety and nutrition can be addressed in a timely manner. Further, FDA believes that cooperative research through JIFSAN will promote the efficient use of the complementary resources (e.g., major instrumentation, space, information and computer technologies, etc.) of both parties. All research will be related to FDA program requirements in food safety and nutrition. Other Federal and State agencies, industry, consumer and trade groups, and international organizations with mutual interests will have opportunities for collaboration. FDA believes that the cooperative research at JIFSAN will enhance the agency's food safety and nutrition programs (e.g., risk assessment, microbiology, food contaminants including natural toxins, food composition, foods for special dietary uses, and advanced studies in micronutrients). The agency and UMCP intend to design the collaborative effort to:

(1) Develop a critical mass of scientific expertise necessary to address ongoing and increasingly complex key public health issues, to provide early warning of emerging problems, to provide support during periodic emergencies and crisis situations (e.g., microbial contamination of apple juice), and to provide scientific expertise in close proximity to FDA administrative offices to expedite regulatory policy and decisions (e.g., petition review). (All official regulatory activities, however, will be performed by FDA employees only);

(2) Provide for more efficient use of current resources devoted to risk assessment research and related activities (e.g., surveillance, modeling, etc.), enhancing the safety of the food supply;

(3) Develop more effective methods for communicating risk associated with both microbial and chemical hazards to the general public by going beyond the study of the science to the study of how that science is heard and understood (risk communication);

(4) Share resources to enhance the research infrastructure and provide for effective use of increasingly sophisticated scientific equipment with high acquisition, installation, and maintenance costs and the corresponding expertise of both parties; and

(5) Establish mechanisms for exchange of technical information and scientific concepts between FDA and other sectors of the food safety and nutrition community (e.g., other Federal and State agencies, industry, academia, consumer and trade groups, and international organizations).

B. Project Emphasis

The purpose of JIFSAN is to develop collaborative partnerships to augment and enhance FDA's scientific expertise in food safety and nutrition. The collaborative work will supplement FDA scientific expertise needed to address increasingly complex problems in such areas as risk assessment, food composition analyses, and other food safety related areas to include: Food safety related to emerging pathogens, contaminants (e.g., industrial chemicals and toxic elements), and natural toxins (e.g., mycotoxins); regulatory science supporting the review of food ingredients and the development of international standards; and nutrition and clinical studies related to nutrient quality, safety, labeling, and patterns of consumer behavior. The downsizing of FDA's food safety and nutrition program has reduced present expertise in some of these areas below critical levels. This loss of expertise has required the agency to find other ways of expanding its science base, such as establishing JIFSAN, a unique partnership between Government and academia.

JIFSAN will be designed to provide the collaborative environment and expertise necessary to conduct advanced research in key areas such as risk analysis (risk assessment, risk management, and risk communication). Risk analysis requires a multidisciplinary approach. The needs of risk analysis are well beyond the core sciences of chemistry, microbiology, toxicology, and traditional food science concepts of food safety and applied nutrition. Risk analysis must draw upon a number of other disciplines, including computer sciences, mathematics and statistics, philosophy of science, economics, communications, and law. The advancement of risk assessment methodologies will ultimately promote efficient and effective risk management (e.g., rational regulation of public health policy) and risk communication approaches. Conducting advanced research in risk analysis will promote the development of risk-based, scientifically supported, safety standards that will result in a safer food supply and can be used to identify priorities in order to more effectively apply available resources.

This collaborative effort will permit the sharing of complementary resources (e.g., major instrumentation, space, and information and computer technologies) and create opportunities to leverage the shrinking resources of both parties so that important national and international issues in food safety and nutrition can be addressed in a timely manner. Many of these issues (i.e., emerging pathogens, natural toxins, toxic element contamination, fortification policy, safety of dietary supplements, etc.) can only be addressed with close cooperation of the public and private sectors. Combining CFSAN's major instrumentation resources and corresponding expertise with UMCP will enhance FDA's access to state-of-the-art instrumentation to conduct research at the forefront of food safety and nutrition sciences. The direct access to the vast library resources on the College Park campus will permit CFSAN to redirect its program from maintaining a classical library system to providing on-line data base access to pertinent scientific literature. The complementary nature of these shared UMCP and FDA facilities will enhance the research infrastructure of both

institutions and reduce costs by avoiding unnecessary duplication. A close working relationship of FDA and University personnel will provide enhanced scientific expertise in advanced techniques for the characterization of biotechnology products as well as expand the current capabilities in research to support regulatory actions and respond to emergency situations.

C. Summary

FDA believes that JIFSAN is a sound investment in the future public health of American consumers. It provides an opportunity for extensive cooperation with University scientists, and it will stimulate collaborative efforts to ensure a safe food supply contributing significantly to implementation of the goals for Government, academia, industry, and consumers to work together to improve food safety. FDA deals with an increasing number of critical and complex food safety issues. In order for FDA to respond rapidly in these situations it requires that FDA scientists be in close proximity with a source of complementary and specialized scientific expertise and facilities to expedite regulatory policy and decisions. The MOU between FDA and UMCP provides the essential foundation for a vigorous, high quality scientific research program to support sound regulatory policy and performance.

The public and FDA will both benefit from the type of collaboration possible at JIFSAN. Scientists from each sector would bring a special perspective to advancing the knowledge of food safety and nutrition sciences. Interaction among those scientists will stimulate creativity and innovation. FDA's participation in this venture will promote a greater awareness and understanding of regulatory science and practice among academic scientists thereby providing economic and program benefits to both. In summary, this collaboration between FDA and UMCP provides an efficient means of remaining current with scientific and technical accomplishments in the areas of food safety and applied nutrition. This will ensure that FDA continues to be best positioned to carry out its statutory responsibilities, respond rapidly in a crisis situation, protect, promote, and enhance the health of the American People.

III. Mechanism of Support

A. Award Instrument

Support for this program, if granted, will be in the form of a cooperative agreement. In 1997, FDA is providing approximately $500,000.00 for this award. It is anticipated that funding will increase in subsequent years. The award will be subject to all policies and requirements that govern the research grant programs of the Public Health Service (PHS), including the provisions of 42 CFR part 52, 45 CFR part 74, and the PHS Grants Policy Statement.

B. Length of Support

The length of support will be 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation, beyond the first year, will be based upon performance during the preceding year and the availability of Federal fiscal year appropriations.

IV. Reasons for Single-Source Selection

FDA believes that there is compelling evidence that UMCP is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. The University is in close proximity to the congressionally directed location of FDA's consolidation of CFSAN and CVM in Prince George's County, MD. The University has vast resources, which complement and greatly expand FDA's research and scientific resources. UMCP is the Washington region's most comprehensive research institution with numerous academic programs relevant to FDA's mission and the resources to support CFSAN's areas of interest, including: Microbiology, chemistry, food science, agriculture, public policy, risk assessment, computational science, economics, and survey methodology. The University serves as the primary center for graduate study and research and provides undergraduate instruction across a broad spectrum of academic disciplines. The University extends its vast intellectual resources to the community through innovative projects designed to serve individuals, governments, and the private sector throughout the State of Maryland, the nation, and the international community. In 1988, the General Assembly of Maryland designated UMCP as the flagship institution for the University of Maryland System which consists of 11 campuses across the State and offers programs at some 200 sites worldwide.

The University is developing four central instrumentation facilities to provide effective use of state-of-the-art scientific instrumentation with high acquisition, installation, and maintenance costs to conduct research at the forefront of science. The central facilities will be the Nuclear Magnetic Resonance Laboratory, Biological Imaging Laboratory, Electron Microscopy Laboratory, and Mass Spectrometry Laboratory. These instrumentation centers will complement CFSAN's resources and expertise and facilitate access to these resources to meet FDA's food safety and nutrition program needs. In addition, the vast library resources on the College Park campus will permit FDA direct access to periodicals and books relevant to the program, as well as access to the collection of libraries on all campuses in the University of Maryland System and use of over 60 automated reference tools in the libraries.

Acknowledging the importance of an interdisciplinary approach to knowledge, the University maintains organized research units outside the usual department structures (i.e., Department of Chemistry and Biochemistry and Department of Molecular, Cell, and Microbial Biology, etc.). Through participation in collaborative projects, FDA will have access to these additional University resources. Several of these research units will complement or meet the programmatic needs of FDA. These units include the Center for Research in Public Communication where cooperative projects related to risk communication studies could be developed, the Survey Research Center and the Institute for Philosophy and Public Policy, which will promote more efficient development and dissemination of public policy, and the Maryland Fire and Rescue Institute, which will facilitate the maintenance of emergency response readiness credentials of the FDA Safety Staff who are responsible for maintaining and ensuring safety and regulatory compliance at FDA facilities where collaborative research is conducted.

Collaboration between the public and the private sector is an efficient means for both FDA and the University to remain current with scientific and technical accomplishments from a food safety and applied nutrition perspective. These collaborative programs will produce generic knowledge and expertise to be used by all segments of the food safety and nutrition community, as well as by public health organizations, other Federal agencies, and academic institutions in the performance of their roles. Harmonizing regulatory activities is but one example of the need for, and use of, this food safety and nutrition knowledge and expertise. The partnership between FDA and UMCP will provide both the technical and educational expertise for effective creation of technology transfer mechanisms that will facilitate the movement of new technology and

provide fundamental food safety and nutrition information to the public and private sector.

V. Reporting Requirements

Program progress reports and financial status reports will be required annually, based on date of award. These reports will be due within 30 days after the end of the budget period. A final program progress report and financial status report will be due 90 days after expiration of the project period of the cooperative agreement.

VI. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

(1) FDA will appoint a project officer or coproject officers who will actively monitor the FDA-supported program under this award.

(2) FDA shall have prior approval on the appointment of all key administrative and scientific personnel proposed by the grantee.

(3) FDA will be directly involved in the guidance and development of the program and of the management structure for the program.

(4) FDA scientists will participate, with the grantee, in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, coauthorship of publications.

Dated: May 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13446 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0183]

Bausch & Lomb, Inc.; Premarket Approval of Bausch & Lomb® Soflens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bausch & Lomb, Inc., Rochester, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 16, 1996, of the approval of the application.

DATES: Petitions for administrative review by June 23, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION: On June 28, 1996, Bausch & Lomb, Inc., Rochester, NY 14692–0450, submitted to CDRH an application for premarket approval of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. The device is a soft (hydrophilic) contact lens and is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this application was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the application substantially duplicates information previously reviewed by this panel.

On December 16, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

The labeling of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 23, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs