3. The _____ postdoctoral research fellow and not more than one other _____ employee at any one time, may work as Guest Workers with the Principal Investigator and may have a reasonable use of research facilities, including laboratory space and equipment, at no charge, as may from time to time be agreed by the Principal Investigator and the appropriate _____ manager.

4. The collaborative research shall be conducted in accordance with the attached research protocol entitled "_____ _____."

5. The Principal Investigator and the postdoctoral research fellow will visit _____ corporate bioscience group once each year. _____ will pay for the accommodations, subsistence, and travel for the postdoctoral research fellow and the Principal Investigator, to the extent permitted by Federal Regulations at 45 CFR 73.735-507(b).

6. Regular monitoring of the research project will be conducted by biannual progress reports prepared jointly by the Principal Investigator and the postdoctoral research fellow, and by biannual meetings between staff from _____ and those directly involved in the research project.

7. <u>Confidentiality of Information</u>

shall treat all data and information relating to the collaborative research program either: (a) submitted in writing by _____

to and suitably indicated or marked as confidential, as trade secrets or commercial or financial information within the exception to the disclosure mandate of the Freedom of Information Act (5 U.S.C. 552(b)(4)), unless otherwise determined by NIH or DHHS FOIA officials or a court of competent jurisdiction. further agrees that such data and information may be disseminated within , but only to the extent necessary to permit performance of obligations under this Agreement. The obligations and restrictions provided in this paragraph shall not apply to whatever portion of such data and information (a) may be in the public domain at the time of disclosure to by _____ or at the time it is derived by and/or _____ in the course of the research program, or after such disclosure or derivation, is made part of the public domain by _____ or a third party not affiliated with or employed by NIAID who is legally in possession of this data or information and is under no obligation to _____ or to to maintain such information confidential; (b) is lawfully made available to by a third party who is not affiliated with or employed by _____ and is under no obligation to _____ to maintain the same confidentiality; or (c) was already known to NIAID at the time of the disclosure to by _____.

8. _____ agrees to cooperate with NIAID in facilitating and creating useful publications in the area of research related to the development of pertussis vaccines, so long as such publications do not result in the disclosure of trade secrets or commercial or financial information treated as priviledged or confidential by under paragraph 7. In order to protect _____ confidential information, agrees to give _____ at least 30 days to review any proposed article resulting from the collaborative research and will not submit any such article for publication prior to obtaining _____ approval. That approval may be withheld only if _____ reasonably determines that the article contains confidential information as defined in paragraph 7. of this Agreement.

9. In accordance with Executive Order 10096, the Department of Health and Human Services (DHHS), the parent agency of . shall have title to any invention developed under this Agreement by employees or by Guest Researchers or Guest Workers. In the event a patent application is filed on such inventions by the DHHS, the DHHS and the . agree to grant to _____ an irrevocable, nonexclusive, royalty-bearing license to make, use, and sell the invention for a period of five (5) years from the date of first commercial sale, or eight (8) years from the date of this license, whichever occurs first, in accordance with the terms and conditions contained in the DHHS Standard Exclusive License

Agreement, (a copy of which is attached hereto and made a part of this agreement attached at Tab B) provided that _____ complies with the requirements of 37 CFR Part 404 (especially §§ 404.5 and 404.8).

10. In the event the and the DHHS determine that no inventions have arisen from the research or that no patent applications will be filed, _____ shall be free to use all information and materials including biological materials, generated or developed during the course of the research, so long as this does not interfere with the use of such information and materials.

11. In the event of any dispute between and _____ arising out this Agreement, which dispute cannot be settled by consultation and discussion between the parties, said dispute shall be referred to the DHHS Assistant Secretary for Health for resolution.

12. The term of this Agreement shall be two (2) years from the date of execution of the Agreement unless extended by written agreement of the parties. This Agreement may be terminated by either party upon 30 days prior written notice and thereafter the parties have no further obligation to supply materials or conduct research. All other rights and obligations set forth herein which vest prior to the termination, shall survive any termination of the Agreement.

13. No indemnification for damages is intended or provided under this Agreement. Each party shall be liable for any damages it incurs as a result of its activities under this Agreement.

14. This Agreement, including any questions concerning its validity or effect, or performance hereunder, or its operation, interpretation of construction, shall be governed and determined in accordance with Federal law.

Date: _____ ___ ___ _____

DRAFT AGREEMENT C.

DRAFT AGREEMENT D

LICENSE AGREEMENT D. DRAFT AGREEMENT D.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

This Agreement, made and entered into this _____ day of _____, 19__, by and between the United States of America, as represented by the Assistant Secretary for Health of the Department of Health and Human Services, hereinafter referred to as the DEPARTMENT, and _____

_____,

hereinafter referred to as the LICENSEE,

WITNESSETH: That whereas the Department is the owner of the entire right, title, and interest in and to United States Patent Number _____, issued _____, and entitled _____

_____

_____;

and

WHEREAS, the Regulations of the Department covering licenses to practice inventions covered by patents and pending patent applications owned by the United States Government, as represented by the Department, provide in 45 C.F.R., Section 6.3 that where it appears that the public interest will be served, the Assistant Secretary for Health may issue licenses providing for limited exclusivity and the payment of royalties to the Department; and

WHEREAS, the Licensee is desirous of obtaining an exclusive license under said patent for the manufacture, use, and sale of the inventions depicted therein throughout the United States, its territories, possessions and dependencies, and the issuance of such a license has been determined to be in the public interest, in order to more adequately and quickly develop the aforesaid invention of the patent for the widest use by the general public; and

WHEREAS, the Licensee has tendered the required sum of two hundred and fifty dollars ($250.00) to the Government to partially reimburse the Government for administrative costs incurred in the issuance of this license and the further processing required during its term;

WHEREAS, the Assistant Secretary for Health has reviewed the request for this license submitted by the Licensee and has determined that extensive development and testing requiring substantial investment of private risk capital in the invention covered by the above patent is needed to bring this invention to the point of practical application, and that the granting of this license is consistent with Section 6.3 of the Department patent regulations,

NOW, THEREFORE, in consideration of the foregoing premises and in consideration of the public interest, and for other good and valuable considerations, the parties hereto agree as follows:

1. DEFINITIONS

Patent Rights - "Patent Rights" means said United States Patent Number _____ and any reissue of such patent, and the invention described therein.

Improvements - "Improvements" means betterment of the processes, intermediates, or the products which are defined by the claims of the above-cited United States patent developed by the Department or party obligated to assign such developments to the Department.

Product - "Product" means any device, material, or subtance which is within the scope of Patent Rights, or which is synthesized by a process within the scope of Patent Rights or employing an intermediate within the scope of Patent Rights.

2. LICENSE

The Department hereby grants and Licensee hereby accepts an exclusive and revocable license under the Patent Rights to make, have made, use, and vend Products, and to use processes coming within the scope of the Patent Rights in the United States of America, its territories, dependencies and possessions, subject to the conditions and limitations hereinafter set forth until _____ years after the first commercial sale of Product by Licensee, or _____ years from the date of this license, whichever occurs first, provided that Licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to the approval of the Department. Any request for such an extension shall be considered on its merits upon written request and justification, it being understood that upon expiration of the period of exclusivity or any extension thereof, the Licensee thereafter for the remaining life of the patent shall have a nonexclusive license. The Licensee shall have the privilege of granting sublicenses with respect to all Patent Rights, or assigning such rights, subject to all the conditions of this Agreement, after

furnishing the Department with a copy of the proposed sublicense or assignment thirty (30) days prior to its execution and receiving no reasonable objection thereto. Such sublicense or assignment shall not be revoked by the Department except under the terms of Paragraph 11 hereof.

3. RESERVATION OF RIGHTS

The license granted in Paragraph 2 above is subject to the reservation by the Department of an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of such invention throughout the world by or on behalf of the United States or any foreign government pursuant to any existing or future treaty.

4. OPTION ON IMPROVEMENTS

The Department will disclose each Improvement to Licensee pursuant to Paragraph 8 hereof. The Licensee may elect, by written notice to the Department within three (3) months after being notified of an Improvement, to file a United States patent application and have said Improvement included as a part of Patent Rights under this Agreement at no increase in royalty. If Licensee does not elect to have an Improvement included as a part of Patent Rights, Licensee and the Department shall have no further obligations hereunder, each to the other, with respect to said Improvement.

5. GOVERNMENT FUNCTIONS - PERFORMANCE

a. The Licensee agrees that development and testing of the invention disclosed in the aforesaid patent or application and marketing of all products under this license will be in accordance with all laws and regulations applicable thereto. This license shall not be construed as restricting any of the rights or powers of the United States to exercise its normal governmental functions in the control of the manufacture, sale, distribution, or consumption of any product within the scope of this license under all pertinent Federal laws or regulations which may now or hereafter be in force.

b. In the event of the exploitation of the Patent Rights outside the United States, Licensee shall comply with all applicable laws and regulations of the United States, including particularly the export control regulations, foreign assets control regulations and transaction control regulations. The license granted herein shall not be construed as exempting Licensee from any of such laws or regulations of the United States.

6. PATENT FILING, PROSECUTION AND MAINTENANCE

The Licensee shall bear the expense of all prosecution of any United States patent applications on Improvements which Licensee has elected to include as part of Patent Rights.

Licensee shall not abandon any patent application on an Improvement, without first offering to transfer prosecution of such application to the Department not less than forty-five (45) days prior to the date a reply to a Patent Office action is due. If the Government does not request a power of attorney to continue prosecution within thirty (30) days of receipt of this offer, the Licensee may permit the application to go abandoned. The Licensee shall, upon request, grant a power of attorney authorizing the Department to inspect and make copies of any documents in the Patent Office pertaining to the prosecution of United States patent applications on any Improvements.

7. DISCLOSURE

The Department shall, upon execution of this Agreement, disclose to Licensee all information, know-how and data relating to Patent Rights, Products, methods for manufacturing Products and formulations containing Products in its possession or under its control, and the Department shall from time to time disclose to Licensee such additional information, know-how and data as it shall acquire or control, all to the extent the Department shall have the right to disclose such information, know-how and data for use by Licensee hereunder without restriction or obligation other than as set forth in this Agreement. The Department shall have the right to publish and make disclosure of any information relating to any subject matter or invention pertaining to the Patent Rights or Improvements, whenever deemed to be in the public interest, provided compliance with Article 4 above of this Agreement has been effected.

8. REPORTS

Licensee shall provide written annual reports to the Department commencing one year from the date of this Agreement regarding the development and commercial use that is being made and is intended to be made of the invention, including the amount of money expended in such development and such other non-proprietary data and information as the Department may

specify. No further annual reports will be required after notification of the first commercial sale of any product embodying the invention unless otherwise requested by the Department.

9. PATENT MARKING

Licensee agrees that it will take all reasonable steps to assure that all packages or containers in which Products are sold by it pursuant to the license herein granted will bear an appropriate legal notice with respect to the patent included in Patent Rights, under which patent the Product is sold. The Department will from time to time supply Licensee the necessary information to be contained in such notices.

10. DEPARTMENT REPRESENTATION OR WARRANTY

a. Warranty - The Department does not warrant that this Product is capable of commercial exploitation, or that the practice by the Licensee of the invention licenses hereunder will be free from any infringement or charges of infringement of any patent or patents. The Department assumes no liability whatsoever that may result from the exercise of the license. The Department, in granting this license, does not represent or warrant the validity of any patent, nor does the Department undertake to prosecute or defend any suit brought by or against the Licensee, or indemnify it for the infringement or enforcement of any patent, nor do the parties hereto waive any rights they may have under the anti-trust laws.

b. Non-Use of Names - This license shall not be construed or in any way be represented as constituting the endorsement by the Government of any product manufactured by the Licensee within the scope of this license, or of the therapeutic utility or safety of any such product.

Licensee shall not use the name of the Government, nor any adaptation of the name of the Government, in any advertising, promotional or sales literature without prior written consent obtained from the Government (as represented by the Assistant Secretary for Health, Department of Health and Human Services) in each case.

11. REVOCATION OF EXCLUSIVE LICENSE

a. The Department reserves the right to revoke the exclusive license granted under Paragraph 2 of this Agreement and/or grant licenses to an applicant on a nonexclusive basis, royalty-free or on terms that are

reasonable under the circumstances if (1) the Licensee or its sublicensees fail to comply with any of the provisions of this Agreement, (2) the Department determines that the public health, safety or welfare requires such action, or (3) within three years after the issue date of this license agreement, the Licensee or its sublicensees have not only failed to bring the invention to the point of practical application, but have also failed to make the invention available for licensing royalty-free or on terms that are reasonable in the circumstances.

Licensee shall be given written notice of any proposed determination pursuant to the provisions of this paragraph not less than thirty (30) days prior to the effective date of such determination and, if it requests, shall be granted a hearing before any such determination is put into effect.

In the event the written notice proposes to revoke the exclusive license on the ground that the Licensee or its sublicensees have failed to comply with any of the provisions of this Agreement (pursuant to clause (1) of this subparagraph), such notice shall not be effective unless, within a period of ninety (90) days (or such longer period as the officer executing this Agreement on behalf of the Department, or his successor, may authorize in writing) from its receipt, the Licensee or its sublicensees shall have failed to cure the asserted noncompliance.

b. If the exclusive license is revoked pursuant to the provisions of subparagraph "a(2)" or "a(3)" above, the Licensee shall have a nonexclusive license under the Patent Rights until expiration thereof. A nonexclusive license obtained pursuant to the terms of this subparagraph shall be revocable if the Licensee, three years after a patent issues on the invention, has failed to bring the invention to the point of practical application.

12. OTHER LICENSEES

In the event that this license becomes nonexclusive, the Department agrees that with respect to licenses to others, if the Department should during the period of this License Agreement grant a license to any person, firm or corporation under more favorable terms, except as to the royalty paid, than those hereby granted to Licensee, the Department will promptly notify Licensee and advise Licensee concerning the differences, in terms between such more favorable license and this License Agreement. Licensee

shall, at Licensee's election, be entitled to the benefit of such more favorable terms as of the date upon which such more favorable license shall become effective.

13. TERMINATION OF AGREEMENT

Licensee shall have the right to terminate this Agreement at any time by giving six (6) months prior written notice to the Department to that effect. From and after the effective date of any termination of this Agreement, neither the Licensee nor the Department shall have further rights, powers, privileges, licenses, obligations or liabilities under any of the provisions of this Agreement.

14. DISPUTES

All disputes concerning the interpretation or application of this License Agreement which are not disposed of by mutual agreement shall be decided by the officer executing this license on behalf of the Government, or his successor, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Licensee. His decision shall be final and conclusive, except on questions of law, unless within thirty (30) days from the date of receipt of such copy the Licensee mails or otherwise furnishes to him a written appeal addressed to the Secretary, Department of Health and Human Services. The decision of the Secretary, or his duly authorized representative for the determination of such appeals, shall be final and conclusive, except on questions of law, unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with appeals under this clause, the Licensee shall be afforded an opportunity to be heard and to offer evidence in support of its appeal.

15. NOTICES

Any report or notice to be given hereunder shall be sent to the following respective addressees:

For the Department:

Assistant Secretary for Health
Department of Health and Human Services
Washington, D. C. 20201

final and conclusive, except on questions of law, unless within thirty (30)

For the Licensee:

_____

_____

_____

16. COVENANT AGAINST CONTINGENT FEES

The Licensee warrants that no person or selling agency has been employed or retained to solicit or secure this license upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Licensee for the purpose of securing business. For breach or violation of this warrant, the Department shall have the right to annul this license without liability.

17. OFFICIAL NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this license or to any benefit that may arise therefrom, but this provision shall not be considered to extend to this license if granted to a corporation for its general benefit.

18. COMPLETE AGREEMENT

This Agreement sets forth the entire understanding between the parties as to the subject matter, and the provisions cannot be modified or changed without the written consent of both parties.

IN WITNESS WHEREOF, the parties hereto have executed this instrument in triplicate by proper persons thereunto duly authorized of the day and year hereinabove written.

UNITED STATES OF AMERICA

By:_____ Date:_____

Title: Assistant Secretary for Health,
Department of Health and Human Services

_____

By:_____ Date:_____

Type Name:_____

Title:_____

if granted to a corporation for its general benefit.

ATTACHMENT III

ATTACHMENT III.

UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

2 NOV 1987

MEMORANDUM FOR Douglas A. Riggs
General Counsel

FROM: Robert Ortner
Under Secretary for Economic Affairs

SUBJECT: Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986

In your memorandum of February 11, 1987, you reviewed this Department's Employee Standards of Conduct for the purposes of the Federal Technology Transfer Act of 1986, and concluded that "our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time." My office is now beginning to prepare materials for use in the Department's laboratories that will establish guidelines for employees in situations likely to arise under the Act. The purpose of this memorandum is to ask you to assign a member of your staff to work with Norm Latker, Director, Office of Federal Technology Management, in the preparation of these guidelines.

These guidelines would address problems that might arise in the course of this Department's implementation of the Act. Some examples of specific questions that should be discussed include:

- Could a Federal employee/inventor accept compensation as a consultant from a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor or co-inventor accept compensation for giving technical advice to a private firm on developing an invention that these employees made under a cooperative agreement with the laboratory?
- Could a Federal employee/inventor invest or become a stockholder in a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor become an officer in a firm which is licensing that employee's invention from the Federal government?

your staff to work with Norm Latker, Director, Office

- Could a Federal employee/inventor remain an employee and become an officer in a firm which, as a result of a cooperative agreement, has been granted in advance a patent license for all that employee's inventions arising under the agreement?

- Would a Federal employee/inventor who obtains a license from the government to use his or her own invention receive 15 percent of the royalties back from the government that he or she paid to the government for the right to use the invention?

- What restrictions are there on a former employee of a Federal laboratory negotiating a cooperative R&D agreement with that Federal laboratory?

- Under what circumstances can an employee of a laboratory leave the laboratory and become an employee of a company which has a cooperative agreement with the laboratory?

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date NOV 24 1987

From Assistant Secretary for Health

Subject Implementation of the Technology Transfer Act

To Heads of PHS Agencies, Center and Institutes
(Delegatees of Technology Transfer Act of 1986)

In followup to the first meeting of the PHS Technology Management Advisory Board, I am providing additional information and guidance to be followed in implementing the Act. This memorandum contains:

(1) Additional information on actions that may be taken under the delegation of October 14, 1987 memorandum and points to be addressed in cooperative research and development agreements (Attachment I Part A and B).

(2) Attachment II presents Draft Model Agreements for cooperative/collaborative research and development agreements and Draft License Agreements:

- o Agreement A--Department of Commerce Model R&D Agreement;
- o Agreement B--PHS Model R&D Agreement;
- o Agreement C--Department of Commerce License Agreement; and
- o Agreement D--PHS License Agreement.

These documents provide a basic guidance that institutes or centers can utilize to shape precise agreements to accomplish the specific tasks of collaboration with other organizations or in licensing of technologies.

(3) Identification of three working groups to support the work of the PHS Technology Management Advisory Board.

A. Implementation Group. This group is to assist, review and facilitate the PHS agencies, centers and institutes in their development of implementation plans required by ASH's October 14 delegation. Further, the group is to establish

appropriate guidelines and procedures for carrying out the Act which includes developing reports, information and data needs and other operational procedures pertinent to the Advisory Board. This group will be chaired by Dr. Ronald Hart, Director NCTR.

B. Operations Group. This group will develop collaborative R/D, licensing and other instruments for carrying out the purposes of the Act. It will provide descriptions of, and access to, tools available to the institutes and centers. As a first agenda item, this group will be responsible for reviewing cooperative research and development and licensing agreement for use by the institutes and centers (see Attachment II above). This group is to be chaired by Dr. Vince DeVita, Director, NCI.

C. Legal Support Group. This group is responsible for assisting the Implementation and Operations Group and in providing legal assistance of issues related to conflict of interest, confidentiality, patent and license agreements, and other support material as requested. It is to chaired by Mr. Robert Lanman, NIH General Counsel.

Full consideration of other cross-cutting issues shall be folded into the work of each group on a best-fit or case-by-case basis as they arise. I will leave selection of the membership of the three working groups to the Chairperson. Further, I would request that those of you who have interest in one or more of these areas contact Chairperson and indicate that interest.

(4) For you information, I am attaching a memo entitled "Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986" by Robert Ortner, Under Secretary for Economic Affair at Department of Commerce, see Attachment III.

Robert E. Windom, M.D.

ATTACHMEMT I PART A

ACTIONS THAT HEADS OF PHS AGENCIES, CENTERS, AND INSTITUTES MAY TAKE UNDER THE OCTOBER 14, 1987 DELEGATION OF AUTHORITY UNDER THE FEDERAL TECHNOLOGY TRANSFER ACT

The Head of a PHS Agency, Center or Institute may:

- Negotiate licensing agreements for Government-owned inventions made within the respective Center, Institute or PHS Agency, or other inventions of Federal employees that may be voluntarily assigned to the government.

- Negotiate and enter into, subject to the approval of the appropriate PHS Agency Head, cooperative research and development agreements, under which the PHS components may accept, retain and use funds, personnel, services, and property and, in exchange, provide personnel, services and property, but not funds.

  Under these agreements, the Institute, Center or Agency may waive the Federal Government's right of ownership to any invention made under the agreement by collaborating party or employee of a collaborating party, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention, or have the invention practiced throughout the world by or on behalf of the Government.

  In addition, a collaborating party may be granted a patent license (exclusive or nonexclusive) or assignment, or option thereto, in any invention made in whole or in part by a Federal employee under the agreement, retaining for the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

- Identify, evaluate and file patent applications on inventions made by employees of the respective Agency, Center or Institute. These activities may be undertaken through the use of distributed royalties or other income.

- Subject to approval by the Assistant Secretary for Health, enter into agreements for the services of other agencies, persons or organizations for invention management and licensing services. The purpose of these services is to facilitate direct support to carry out the work of the institute and center in transferring technology to bring the result of research to the marketplace and patient.

- Use royalty income distributed to the PHS component to reward scientific, engineering and technical employees of the laboratory, for payment of expenses incidental to the administration and licensing of inventions, to further scientific exchange among the Government-operated laboratories, and for education and training of employees consistent with the research and development mission of the Agency, and for other activities that increase the potential for transfer of technology.

- Heads of the PHS agencies shall receive all royalty or other income produced under cooperative research and development and license agreements for distribution to their respective Centers and Institutes. After paying the inventor's share, the majority share of royalties and income shall be returned and utilized by the Center or Institute where the invention occurred. Any remaining amount shall be used as directed by the Agency, either at the Agency or at the Agency's other Centers and Institutes, in accordance with the requirements of the Act.

- Institutes and Centers may enter into Cooperative Research and Development Agreements negotiated by the Centers and Institutes. Part B of Attachment I identifies points to be considered in negotiating and finalizing such agreements. It should be noted that the PHS Agency Head has thirty (30) days to review and disapprove in writing to the Institute or Center Director.

Topics to be Addressed in Cooperative Research and Development Agreements

A Cooperative Research and Development Agreement should contain provisions addressing the following subjects:

1. The effective date.

2. Principal investigator(s) for the Government and for the collaborating party.

3. Funds, personnel, services and property to be provided by the collaborating party.

4. Personnel, services and property to be provided by the Government.

5. Retention and ownership of property in the event of termination.

6. Delineation of the research encompassed by the agreement.

7. Procedures for interaction between the collaborating parties.

8. Provisions protecting the Government's right to publish research results while giving the collaborating party an opportunity to protect its proprietary information.

9. Provisions for the protection of proprietary information, including appropriate references to the Freedom of Information Act. Such provisions should reference 35 U.S.C. which authorizes federal agencies to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed.

10. Patent rights clauses, which may include the granting to the collaborating party of an exclusive or nonexclusive license to inventions made in whole or impart by a Federal employee and a waiver of any Government rights to an invention made in whole or impart by a collaborating party or an employee of a collaborating party. Both of the foregoing are subject

to retention by the government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the government.

11. A disputes resolution clause, providing that disputes which cannot be resolved by the parties are to be resolved by the Head of the Agency.

12. A clause addressing identification. The Government cannot agree to identify the collaborating party for damages, nor may the Government agree to pay attorney's fees or waive any of its rights in litigation that might arise regarding the agreement but may permit a collaborating party to assume responsibility to pursue of patents licensed by government.

13. The term of the agreement.

14. Procedures for termination of the agreement and a statement of what rights survive termination.

15. A statement as to what law governs the validity and effect of the agreement. Federal law must control, but in the absence of any conflicting Federal law, State law may control.

DRAFT Agreement B.

Collaborative Research Agreement

This Agreement, effective _____, 1986, is by and between _____ and the _____ (hereinafter referred to as _____, National Institutes of Health (NIH), a component agency of the Department of Health and Human Services (DHHS).

1. During the term of this Agreement, _____ will provide through the _____ salary and salary dependent charges for a postdoctoral research worker (the _____ postdoctoral research fellow), who will work on the project for _____ as a Guest Worker at NIH, miscellaneous supplies and expense items in the amount of $_____ for the first year and for the second year commencing October 1, 1987, $_____.

2. The Principal Investigator for the study is Dr. _____. The Principal Investigator is responsible for performing the work described in the research protocol attached at Tab A. In the event the Principal Investigator becomes unable to complete the protocol for any reason, _____ and _____ may mutually agree to a substitute Principal Investigator, in which event this Agreement shall continue in full force and effect. If _____ and _____ cannot agree on a substitute, this Agreement shall immediately terminate.

DRAFT Agreement B.

Collaborative Research Agreement

This Agreement, effective _____, 1986, is by and between _____ and the _____ (hereinafter referred to as _____, National Institutes of Health (NIH), a component agency of the Department of Health and Human Services (DHHS).

1. During the term of this Agreement, _____ will provide through the _____ salary and salary dependent charges for a postdoctoral research worker (the _____ postdoctoral research fellow), who will work on the project for _____ as a Guest Worker at NIH, miscellaneous supplies and expense items in the amount of $_____ for the first year and for the second year commencing October 1, 1987, $_____.

2. The Principal Investigator for the study is Dr. _____. The Principal Investigator is responsible for performing the work described in the research protocol attached at Tab A. In the event the Principal Investigator becomes unable to complete the protocol for any reason, _____ and _____ may mutually agree to a substitute Principal Investigator, in which event this Agreement shall continue in full force and effect. If _____ and _____ cannot agree on a substitute, this Agreement shall immediately terminate.

3. The _____ postdoctoral research fellow and not more than one other _____ employee at any one time, may work as Guest Workers with the Principal Investigator and may have a reasonable use of research facilities, including laboratory space and equipment, at no charge, as may from time to time be agreed by the Principal Investigator and the appropriate _____ manager.

4. The collaborative research shall be conducted in accordance with the attached research protocol entitled "_____ _____."

5. The Principal Investigator and the postdoctoral research fellow will visit _____ corporate bioscience group once each year. _____ will pay for the accommodations, subsistence, and travel for the postdoctoral research fellow and the Principal Investigator, to the extent permitted by Federal Regulations at 45 CFR 73.735-507(b).

6. Regular monitoring of the research project will be conducted by biannual progress reports prepared jointly by the Principal Investigator and the postdoctoral research fellow, and by biannual meetings between staff from _____ and those directly involved in the research project.

7. Confidentiality of Information

shall treat all data and information relating to the collaborative research program either: (a) submitted in writing by _____

to and suitably indicated or marked as confidential, as trade secrets or commercial or financial information within the exception to the disclosure mandate of the Freedom of Information Act (5 U.S.C. 552(b)(4)), unless otherwise determined by NIH or DHHS FOIA officials or a court of competent jurisdiction. further agrees that such data and information may be disseminated within , but only to the extent necessary to permit performance of obligations under this Agreement. The obligations and restrictions provided in this paragraph shall not apply to whatever portion of such data and information (a) may be in the public domain at the time of disclosure to by _____ or at the time it is derived by and/or _____ in the course of the research program, or after such disclosure or derivation, is made part of the public domain by _____ or a third party not affiliated with or employed by NIAID who is legally in possession of this data or information and is under no obligation to _____ or to to maintain such information confidential; (b) is lawfully made available to by a third party who is not affiliated with or employed by _____ and is under no obligation to _____ to maintain the same confidentiality; or (c) was already known to NIAID at the time of the disclosure to by _____.

8. _____ agrees to cooperate with NIAID in facilitating and creating useful publications in the area of research related to the development of pertussis vaccines, so long as such publications do not result in the disclosure of trade secrets or commercial or financial information treated as priviledged or confidential by under paragraph 7. In order to protect _____ confidential information, agrees to give _____ at least 30 days to review any proposed article resulting from the collaborative research and will not submit any such article for publication prior to obtaining _____ approval. That approval may be withheld only if _____ reasonably determines that the article contains confidential information as defined in paragraph 7. of this Agreement.

9. In accordance with Executive Order 10096, the Department of Health and Human Services (DHHS), the parent agency of . shall have title to any invention developed under this Agreement by employees or by Guest Researchers or Guest Workers. In the event a patent application is filed on such inventions by the DHHS, the DHHS and the . agree to grant to _____ an irrevocable, nonexclusive, royalty-bearing license to make, use, and sell the invention for a period of five (5) years from the date of first commercial sale, or eight (8) years from the date of this license, whichever occurs first, in accordance with the terms and conditions contained in the DHHS Standard Exclusive License

Agreement, (a copy of which is attached hereto and made a part of this agreement attached at Tab B) provided that _____ complies with the requirements of 37 CFR Part 404 (especially §§ 404.5 and 404.8).

10. In the event the and the DHHS determine that no inventions have arisen from the research or that no patent applications will be filed, _____ shall be free to use all information and materials including biological materials, generated or developed during the course of the research, so long as this does not interfere with the use of such information and materials.

11. In the event of any dispute between and _____ arising out this Agreement, which dispute cannot be settled by consultation and discussion between the parties, said dispute shall be referred to the DHHS Assistant Secretary for Health for resolution.

12. The term of this Agreement shall be two (2) years from the date of execution of the Agreement unless extended by written agreement of the parties. This Agreement may be terminated by either party upon 30 days prior written notice and thereafter the parties have no further obligation to supply materials or conduct research. All other rights and obligations set forth herein which vest prior to the termination, shall survive any termination of the Agreement.

13. No indemnification for damages is intended or provided under this Agreement. Each party shall be liable for any damages it incurs as a result of its activities under this Agreement.

14. This Agreement, including any questions concerning its validity or effect, or performance hereunder, or its operation, interpretation of construction, shall be governed and determined in accordance with Federal law.

Date: _____ ___ ___ _____

LICENSE AGREEMENT D. DRAFT AGREEMENT D.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

This Agreement, made and entered into this _____ day of _____, 19__, by and between the United States of America, as represented by the Assistant Secretary for Health of the Department of Health and Human Services, hereinafter referred to as the DEPARTMENT, and _____

_____,

hereinafter referred to as the LICENSEE,

WITNESSETH: That whereas the Department is the owner of the entire right, title, and interest in and to United States Patent Number _____, issued _____, and entitled _____

_____

_____;

and

WHEREAS, the Regulations of the Department covering licenses to practice inventions covered by patents and pending patent applications owned by the United States Government, as represented by the Department, provide in 45 C.F.R., Section 6.3 that where it appears that the public interest will be served, the Assistant Secretary for Health may issue licenses providing for limited exclusivity and the payment of royalties to the Department; and

WHEREAS, the Licensee is desirous of obtaining an exclusive license under said patent for the manufacture, use, and sale of the inventions depicted therein throughout the United States, its territories, possessions and dependencies, and the issuance of such a license has been determined to be in the public interest, in order to more adequately and quickly develop the aforesaid invention of the patent for the widest use by the general public; and

WHEREAS, the Licensee has tendered the required sum of two hundred and fifty dollars ($250.00) to the Government to partially reimburse the Government for administrative costs incurred in the issuance of this license and the further processing required during its term;

WHEREAS, the Assistant Secretary for Health has reviewed the request for this license submitted by the Licensee and has determined that extensive development and testing requiring substantial investment of private risk capital in the invention covered by the above patent is needed to bring this invention to the point of practical application, and that the granting of this license is consistent with Section 6.3 of the Department patent regulations,

NOW, THEREFORE, in consideration of the foregoing premises and in consideration of the public interest, and for other good and valuable considerations, the parties hereto agree as follows:

1. DEFINITIONS

Patent Rights - "Patent Rights" means said United States Patent Number _____ and any reissue of such patent, and the invention described therein.

Improvements - "Improvements" means betterment of the processes, intermediates, or the products which are defined by the claims of the above-cited United States patent developed by the Department or party obligated to assign such developments to the Department.

Product - "Product" means any device, material, or subtance which is within the scope of Patent Rights, or which is synthesized by a process within the scope of Patent Rights or employing an intermediate within the scope of Patent Rights.

2. LICENSE

The Department hereby grants and Licensee hereby accepts an exclusive and revocable license under the Patent Rights to make, have made, use, and vend Products, and to use processes coming within the scope of the Patent Rights in the United States of America, its territories, dependencies and possessions, subject to the conditions and limitations hereinafter set forth until _____ years after the first commercial sale of Product by Licensee, or _____ years from the date of this license, whichever occurs first, provided that Licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to the approval of the Department. Any request for such an extension shall be considered on its merits upon written request and justification, it being understood that upon expiration of the period of exclusivity or any extension thereof, the Licensee thereafter for the remaining life of the patent shall have a nonexclusive license. The Licensee shall have the privilege of granting sublicenses with respect to all Patent Rights, or assigning such rights, subject to all the conditions of this Agreement, after

furnishing the Department with a copy of the proposed sublicense or assignment thirty (30) days prior to its execution and receiving no reasonable objection thereto. Such sublicense or assignment shall not be revoked by the Department except under the terms of Paragraph 11 hereof.

3. RESERVATION OF RIGHTS

The license granted in Paragraph 2 above is subject to the reservation by the Department of an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of such invention throughout the world by or on behalf of the United States or any foreign government pursuant to any existing or future treaty.

4. OPTION ON IMPROVEMENTS

The Department will disclose each Improvement to Licensee pursuant to Paragraph 8 hereof. The Licensee may elect, by written notice to the Department within three (3) months after being notified of an Improvement, to file a United States patent application and have said Improvement included as a part of Patent Rights under this Agreement at no increase in royalty. If Licensee does not elect to have an Improvement included as a part of Patent Rights, Licensee and the Department shall have no further obligations hereunder, each to the other, with respect to said Improvement.

5. GOVERNMENT FUNCTIONS - PERFORMANCE

a. The Licensee agrees that development and testing of the invention disclosed in the aforesaid patent or application and marketing of all products under this license will be in accordance with all laws and regulations applicable thereto. This license shall not be construed as restricting any of the rights or powers of the United States to exercise its normal governmental functions in the control of the manufacture, sale, distribution, or consumption of any product within the scope of this license under all pertinent Federal laws or regulations which may now or hereafter be in force.

b. In the event of the exploitation of the Patent Rights outside the United States, Licensee shall comply with all applicable laws and regulations of the United States, including particularly the export control regulations, foreign assets control regulations and transaction control regulations. The license granted herein shall not be construed as exempting Licensee from any of such laws or regulations of the United States.

6. PATENT FILING, PROSECUTION AND MAINTENANCE

The Licensee shall bear the expense of all prosecution of any United States patent applications on Improvements which Licensee has elected to include as part of Patent Rights.

Licensee shall not abandon any patent application on an Improvement, without first offering to transfer prosecution of such application to the Department not less than forty-five (45) days prior to the date a reply to a Patent Office action is due. If the Government does not request a power of attorney to continue prosecution within thirty (30) days of receipt of this offer, the Licensee may permit the application to go abandoned. The Licensee shall, upon request, grant a power of attorney authorizing the Department to inspect and make copies of any documents in the Patent Office pertaining to the prosecution of United States patent applications on any Improvements.

7. DISCLOSURE

The Department shall, upon execution of this Agreement, disclose to Licensee all information, know-how and data relating to Patent Rights, Products, methods for manufacturing Products and formulations containing Products in its possession or under its control, and the Department shall from time to time disclose to Licensee such additional information, know-how and data as it shall acquire or control, all to the extent the Department shall have the right to disclose such information, know-how and data for use by Licensee hereunder without restriction or obligation other than as set forth in this Agreement. The Department shall have the right to publish and make disclosure of any information relating to any subject matter or invention pertaining to the Patent Rights or Improvements, whenever deemed to be in the public interest, provided compliance with Article 4 above of this Agreement has been effected.

8. REPORTS

Licensee shall provide written annual reports to the Department commencing one year from the date of this Agreement regarding the development and commercial use that is being made and is intended to be made of the invention, including the amount of money expended in such development and such other non-proprietary data and information as the Department may

specify. No further annual reports will be required after notification of the first commercial sale of any product embodying the invention unless otherwise requested by the Department.

9. PATENT MARKING

Licensee agrees that it will take all reasonable steps to assure that all packages or containers in which Products are sold by it pursuant to the license herein granted will bear an appropriate legal notice with respect to the patent included in Patent Rights, under which patent the Product is sold. The Department will from time to time supply Licensee the necessary information to be contained in such notices.

10. DEPARTMENT REPRESENTATION OR WARRANTY

a. Warranty - The Department does not warrant that this Product is capable of commercial exploitation, or that the practice by the Licensee of the invention licenses hereunder will be free from any infringement or charges of infringement of any patent or patents. The Department assumes no liability whatsoever that may result from the exercise of the license. The Department, in granting this license, does not represent or warrant the validity of any patent, nor does the Department undertake to prosecute or defend any suit brought by or against the Licensee, or indemnify it for the infringement or enforcement of any patent, nor do the parties hereto waive any rights they may have under the anti-trust laws.

b. Non-Use of Names - This license shall not be construed or in any way be represented as constituting the endorsement by the Government of any product manufactured by the Licensee within the scope of this license, or of the therapeutic utility or safety of any such product.

Licensee shall not use the name of the Government, nor any adaptation of the name of the Government, in any advertising, promotional or sales literature without prior written consent obtained from the Government (as represented by the Assistant Secretary for Health, Department of Health and Human Services) in each case.

11. REVOCATION OF EXCLUSIVE LICENSE

a. The Department reserves the right to revoke the exclusive license granted under Paragraph 2 of this Agreement and/or grant licenses to an applicant on a nonexclusive basis, royalty-free or on terms that are

reasonable under the circumstances if (1) the Licensee or its sublicensees fail to comply with any of the provisions of this Agreement, (2) the Department determines that the public health, safety or welfare requires such action, or (3) within three years after the issue date of this license agreement, the Licensee or its sublicensees have not only failed to bring the invention to the point of practical application, but have also failed to make the invention available for licensing royalty-free or on terms that are reasonable in the circumstances.

Licensee shall be given written notice of any proposed determination pursuant to the provisions of this paragraph not less than thirty (30) days prior to the effective date of such determination and, if it requests, shall be granted a hearing before any such determination is put into effect.

In the event the written notice proposes to revoke the exclusive license on the ground that the Licensee or its sublicensees have failed to comply with any of the provisions of this Agreement (pursuant to clause (1) of this subparagraph), such notice shall not be effective unless, within a period of ninety (90) days (or such longer period as the officer executing this Agreement on behalf of the Department, or his successor, may authorize in writing) from its receipt, the Licensee or its sublicensees shall have failed to cure the asserted noncompliance.

b. If the exclusive license is revoked pursuant to the provisions of subparagraph "a(2)" or "a(3)" above, the Licensee shall have a nonexclusive license under the Patent Rights until expiration thereof. A nonexclusive license obtained pursuant to the terms of this subparagraph shall be revocable if the Licensee, three years after a patent issues on the invention, has failed to bring the invention to the point of practical application.

12. OTHER LICENSEES

In the event that this license becomes nonexclusive, the Department agrees that with respect to licenses to others, if the Department should during the period of this License Agreement grant a license to any person, firm or corporation under more favorable terms, except as to the royalty paid, than those hereby granted to Licensee, the Department will promptly notify Licensee and advise Licensee concerning the differences, in terms between such more favorable license and this License Agreement. Licensee

executing this Agreement on behalf of the Department, or his successor, may

shall, at Licensee's election, be entitled to the benefit of such more favorable terms as of the date upon which such more favorable license shall become effective.

13. TERMINATION OF AGREEMENT

Licensee shall have the right to terminate this Agreement at any time by giving six (6) months prior written notice to the Department to that effect. From and after the effective date of any termination of this Agreement, neither the Licensee nor the Department shall have further rights, powers, privileges, licenses, obligations or liabilities under any of the provisions of this Agreement.

14. DISPUTES

All disputes concerning the interpretation or application of this License Agreement which are not disposed of by mutual agreement shall be decided by the officer executing this license on behalf of the Government, or his successor, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Licensee. His decision shall be final and conclusive, except on questions of law, unless within thirty (30) days from the date of receipt of such copy the Licensee mails or otherwise furnishes to him a written appeal addressed to the Secretary, Department of Health and Human Services. The decision of the Secretary, or his duly authorized representative for the determination of such appeals, shall be final and conclusive, except on questions of law, unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with appeals under this clause, the Licensee shall be afforded an opportunity to be heard and to offer evidence in support of its appeal.

15. NOTICES

Any report or notice to be given hereunder shall be sent to the following respective addressees:

For the Department:

Assistant Secretary for Health
Department of Health and Human Services
Washington, D. C. 20201

For the Licensee:

_____

_____

_____

16. COVENANT AGAINST CONTINGENT FEES

The Licensee warrants that no person or selling agency has been employed or retained to solicit or secure this license upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Licensee for the purpose of securing business. For breach or violation of this warrant, the Department shall have the right to annul this license without liability.

17. OFFICIAL NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this license or to any benefit that may arise therefrom, but this provision shall not be considered to extend to this license if granted to a corporation for its general benefit.

18. COMPLETE AGREEMENT

This Agreement sets forth the entire understanding between the parties as to the subject matter, and the provisions cannot be modified or changed without the written consent of both parties.

IN WITNESS WHEREOF, the parties hereto have executed this instrument in triplicate by proper persons thereunto duly authorized of the day and year hereinabove written.

UNITED STATES OF AMERICA

By:_____ Date:_____

Title: Assistant Secretary for Health,
Department of Health and Human Services

_____

By:_____ Date:_____

Type Name:_____

Title:_____

ATTACHMENT III