

**INVOICE and PURCHASE AGREEMENT for BabyBIG®**

Patient Name _____

Invoice Number _____

Hospital Name _____

Hospital P.O. Number _____

City, State _____

Date _____

GENERAL INSTRUCTIONS:

1. If possible, obtain an institutional Purchase Order Number (usually issued by the Pharmacy Department) and enter it in the above space.
2. Obtain the duly authorized institutional signature on page 7 of this Agreement. **Make a copy of the signed Invoice and Purchase Agreement (IPA) for delivery to your institution's Accounts Payable department.**
3. Hand-deliver the copy of the IPA to your hospital's Accounts Payable department for completing the wire transfer of funds.
4. Fax the IPA to the Infant Botulism Treatment and Prevention Program (IBTPP) at (510) 231-7609 (normal business hours) or (510) 217-4449 (nights, weekends and holidays).
5. Return the IPA with original signatures to IBTPP by overnight courier (air bill enclosed).
6. **Wire the current \$45,300-- fee for BabyBIG® within five (5) business days, in order to avoid liability for late penalties (see p. 2, paragraph 1, and p. 6, paragraphs 12 and 13).** Funds can be wired from your institution's regular bank. Use the instructions below. Be sure to include the invoice number.
7. If you have any questions, please call Stacy Russ, Administrative Manager, Infant Botulism Treatment and Prevention Program, at (510) 231-7600.

WIRE TRANSFER INSTRUCTIONS:

1. Name of Bank: Bank of America
Address: 555 Capital Mall
Sacramento CA 95814
2. Account Name: Department of Health Services BabyBIG® Fund 0272
3. Bank Account Number: 14364-80640
4. ABA Number: # 0260-0959-3
5. Instructions/Description: Invoice # _____
Deposit to BabyBIG® Fund 0272.

PURCHASE AGREEMENT FOR BabyBIG®
[Botulism Immune Globulin Intravenous (Human)]

This Agreement (Agreement) is made and entered into this ____ day of _____, 20 ____ by and between the State of California, through its duly elected or appointed, qualified and acting officer Mark Starr, D.V.M., M.P.V.M., Acting Chief, Division of Communicable Disease Control, California Department of Health Services, with a principal place of business located at 1501 Capitol Avenue, Suite 71-2048, Sacramento, CA 95814, acting for the California Department of Health Services' Infant Botulism Treatment and Prevention Program, which has its principal place of business located at 850 Marina Bay Parkway, Room E361, Richmond, California 94804, and the _____
(Hospital/Medical Center), with a principal place of business located at _____, hereafter called the Purchaser.

Recitals:

1. Whereas, in 1989 the California Department of Health Services (CDHS) in a Cooperative Agreement with the U.S. Food and Drug Administration (FDA) undertook the development and testing of Botulism Immune Globulin Intravenous (Human) (BIG-IV) for the treatment of the orphan disease of infant botulism; and,
2. Whereas, BIG-IV was designated by FDA in 1989 to be an Orphan Drug that is sponsored by CDHS; and,
3. Whereas, CDHS conducted a randomized, double-masked, placebo-controlled, statewide pivotal clinical trial between 1992 and 1997, which demonstrated that BIG-IV is safe and effective for the treatment of infant botulism by reducing average hospital stay and average hospital costs by more than 60% each; and,
4. Whereas, CDHS extended the pivotal clinical trial results with a nationwide "open-label" study between 1998 and 2003, which demonstrated that BIG-IV shortened average hospital stay from 5.7 weeks to 2.1 weeks and reduced average hospital costs from \$151,800 to \$51,500 *per patient*; and
5. Whereas, on 23 October 2003 FDA licensed BIG-IV as BabyBIG® for the treatment of infant botulism types A and B; and,
6. Whereas, California Health & Safety Code Sections 123700-123709 established the Infant Botulism Treatment and Prevention Program (IBTPP) within CDHS for the purposes of a) assuring the on-going availability of a national supply of BabyBIG®, b) providing statewide diagnostic and consultative services for infant botulism, and c) reducing the occurrence of infant botulism and related illnesses in California; and,
7. Whereas, California Health & Safety Code Section 123704 requires the IBTPP to distribute BabyBIG® in California and nationwide to patients suspected of having infant botulism in accord with federal law; and,

8. Whereas, federal law authorizes and State law requires that CDHS as Sponsor of BabyBIG[®] charge a fee in exchange for BabyBIG[®] in order to meet but not exceed the IBTPP operational expenses, including the developmental and on-going production costs of BabyBIG[®]; and,
9. Whereas, State law mandates that IBTPP investigate ways to improve the treatment of infant botulism, including making technical improvements to BabyBIG[®], and develop and implement control measures for the prevention of infant botulism and related illnesses; and,
10. Whereas, federal law [21CFR314.80(c)(2) and 21CFR314.81(b)(2)] requires CDHS as the Sponsor of BabyBIG[®] to collect specified information, and federal law also authorizes hospitals to release patient "protected health information" without obtaining the subject's consent to the sponsor of a licensed medical product [45CFR164.512(b)(1)(iii)]; and,
11. Whereas, CDHS as the Sponsor of BabyBIG[®] is required to provide such information to FDA to comply with licensure maintenance requirements for BabyBIG[®]; and,

WHEREAS, _____ Hospital has admitted a patient whom it believes has infant botulism and wishes to procure BabyBIG[®] for the treatment of this patient;

NOW, THEREFORE, in consideration of the mutual covenants, conditions, agreements, and stipulations contained herein, and with the intent to be legally bound thereby, the parties do agree as follows:

Terms and Payment:

1. a. Purchaser agrees to pay to CDHS/IBTPP in cash by **wire transfer only** a fee of \$ 45,300.00 (Forty Five Thousand Three Hundred DOLLARS) for the BabyBIG[®] needed to treat this patient.
- b. **Purchaser agrees that the fee for BabyBIG[®] is the retail price for this product and agrees not to add any mark-ups to this price when billing third parties for BabyBIG[®].**
- c. Payment must be received within **five (5) business days** of signing this agreement.
- d. The invoice number for this transaction is _____.
(obtain from IBTPP)
- e. The fee wire transfer instructions are as follows: a) Name of Bank: Bank of America, 555 Capital Mall, Sacramento, CA 95814, b) Account Name: Department of Health Services BabyBIG[®] Fund 0272, c) Bank Account Number: 14364-80640, d) ABA #: 0260-0959-3,
- f. **Information to include on transfer: "Deposit to _____ BabyBIG[®]/Fund 0272."**
(obtain from IBTPP)
- g. Hospital P.O. number, **if known:** _____.
[For any difficulties encountered in using these instructions, please contact Cora Calapine, Senior Accounting Officer, California Department of Health Services, at (916) 552-8414 (telephone) and (916) 552-8399 (fax).]

2. Purchaser shall arrange and pay for shipment and delivery of BabyBIG[®] to Purchaser.

Request for BabyBIG[®]

3. Purchaser agrees to designate an attending staff physician for this patient. Purchaser shall require the attending staff physician to provide the following information to the IBTPP, as authorized by 45 CFR 164.512(b)(1)(iii):
 - a. Date and time of notification of public health officials of this case of possible infant botulism and of the specific arrangements made for diagnostic testing of fecal and/or enema specimen(s) for mandatory establishment of the diagnosis of infant botulism, and
 - b. Additional information as specified in paragraphs 4, 5 and 6 of this Agreement to enable the IBTPP to investigate ways to improve the treatment of infant botulism.
4. Purchaser agrees to provide the following information and documents by electronic transfer (fax) at the time of its written request (i.e., the duly-signed Invoice and Purchase Agreement) for BabyBIG[®]:
 - a. Name, address, telephone number and date of birth of the patient to be treated with BabyBIG[®].
 - b. Name, address and telephone number of parent(s) or guardian(s) of the patient to be treated with BabyBIG[®].
 - c. Date(s) of admission to Purchaser's hospital and of admission to any hospital for the present illness that is considered to be probable infant botulism.
 - d. Admission diagnosis or diagnoses.
 - e. Hospital record number.
 - f. Name, address, business telephone and telefax number of patient's attending physician.
 - g. Patient's admission history, physical examination findings, and results of laboratory and diagnostic studies.
 - h. Treatment plan and medications prescribed, or equivalent document.
5. Purchaser agrees to provide the following information to CDHS/IBTPP after administration of BabyBIG[®] to patient and within 24 hours of the occurrence or the recognition of occurrence:
 - a. Any adverse reaction in the patient treated with BabyBIG[®], either suspected or actual, that occurs within 5 days of administration of BabyBIG[®].
 - b. The circumstances under which any adverse reaction, either suspected or actual, occurred within 5 days of administration of BabyBIG[®].

- c. The reasons why the reaction may or may not have been related to the administration of BabyBIG[®] to the patient.
 - d. The transmission, or possible transmission, of any virus or other transmissible etiological agent to the patient due to administration of BabyBIG[®].
6. Purchaser agrees to provide the following information at no charge to CDHS/IBTPP within two weeks after the patient treated with BabyBIG[®] has been discharged from the hospital:
- a. Admission and discharge summaries, and other medical record information if requested, e.g., nurses' notes, medication records, etc.
 - b. A listing of hospital charges, costs, and reimbursements for the patient's hospital stay.

Delivery of BabyBIG[®]

7. Upon receipt by facsimile (fax) of this executed Agreement by Purchaser, together with the information listed in Paragraph 4, CDHS/IBTPP agrees to provide promptly to the Purchaser the BabyBIG[®] needed to treat this patient. BabyBIG[®] will be made available for pick up by the Purchaser's courier by the IBTPP's contract distributor, FFF Enterprises, Inc., 41093 County Center Drive, Temecula, California 92591.

Liability

8. Purchaser shall be liable for loss or damage of BabyBIG[®] which occurs in transit or after transit subsequent to delivery of BabyBIG[®] to Purchaser or Purchaser's courier at 41093 County Center Drive, Temecula, California 92591.

Indemnification

9. Purchaser agrees to indemnify, defend and hold harmless the CDHS, its officers, agents and employees from any and all liability, demands, claims, costs, losses, damages, recoveries, settlements, and expenses (including interest, penalties, attorney fees, accounting fees, and expert witness fees) incurred by Purchaser accruing or resulting to any person, firm or corporation who may be injured or damaged by the Purchaser as a result of Purchaser's action or inaction in the performance of this Agreement.
10. CDHS/IBTPP warrants that BabyBIG[®] will conform to the specifications and descriptions incorporated herein. **IBTPP MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, AND SPECIFICALLY MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN THE PURPOSES DETAILED IN THE SPECIFICATIONS AND DESCRIPTION IN THE U.S. FDA-APPROVED PACKAGE INSERT FOR BabyBIG[®], INCORPORATED HEREIN AS EXHIBIT A.**

Remedies for Breach

11. All parties recognize and agree that information related to treatment with BabyBIG[®] and the rights and obligations set forth in this Agreement are unique and are of such a nature as to be inherently difficult or impossible to value monetarily. Therefore, in the event of a breach of this Agreement by any party, an action at law for damages or other remedies at law would be inadequate to protect the unique rights and interests of the parties to this Agreement. Accordingly, in any controversy concerning the purchase or sale of BabyBIG[®] or of any of the terms of this Agreement, its provisions shall be enforceable by specific performance. This remedy shall not be exclusive and shall be in addition to any other remedy available to the parties.
12. Purchaser acknowledges that IBTPP is relying on Purchaser to deliver the fee for BabyBIG[®] described in Paragraph 1 and the information described in Paragraphs 4, 5 and 6 within the time indicated in the terms of this Agreement. If Purchaser fails to deliver the fee or provide any item of information in accordance with the terms of this Agreement, Purchaser shall pay to IBTPP as liquidated damages and not as a penalty the amount of \$100.00 (ONE HUNDRED DOLLARS) per day for each day delivery is delayed beyond the scheduled date.

Miscellaneous

13. Without the written consent of the CDHS/IBTPP, this Agreement is not assignable by Purchaser either in whole or in part.
14. This Agreement constitutes a valid and binding obligation on each party, enforceable in accordance with its terms.
15. No consent or approval of any other person or governmental authority is necessary for this Agreement to be effective.
16. This Agreement constitutes the full understanding of the parties and a complete and exclusive statement of the terms of the Agreement.
17. This Agreement shall be governed by and construed in accordance with the laws of California.
18. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of the Agreement shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of the Agreement.
19. No amendment of the terms of this Agreement shall be valid unless made in writing and signed by the parties hereto, and no oral understanding or agreement not incorporated herein, shall be binding on any of the parties hereto.

AUTHORIZED OFFICIAL OF THE PURCHASING INSTITUTION:

Signature of Authorized Official

Hospital Name

Printed Name of Authorized Official

Street Address

Title of Authorized Official

City and State

Date

Telephone Number

Hospital DEA Number (required)

CPT Number for BabyBIG® is 90288
Current Procedural Terminology (CPT)

National Drug Code (NDC #): 68403-1100-6

Contact person in Accounts Payable to whom the Authorized Official will promptly send a copy of this Agreement:

Name (Accounts Payable)

Title (Accounts Payable)

Phone Number for Accounts Payable Dept.

Fax Number for Accounts Payable Dept.

(Printed Name of Hospital CFO or CEO)

(Telephone # of Hospital CFO or CEO)

AUTHORIZED OFFICIAL OF THE CALIFORNIA DEPARTMENT OF HEALTH SERVICES:

Mark Starr, D.V.M.
Acting Chief
Division of Communicable Disease Control

May 1, 2004
Date