



DEC 11 1997

Dear Biologic Product Manufacturer:

As you may know, several lots of human blood-derived materials including albumin and transferrin have been withdrawn from the market because the lots were manufactured from plasma pools containing units collected from donor(s) subsequently diagnosed with Creutzfeldt-Jakob Disease (CJD) or at increased risk for development of CJD. A list of withdrawn human blood-derived materials is enclosed; please notify us of any additional products that may not be on this list.

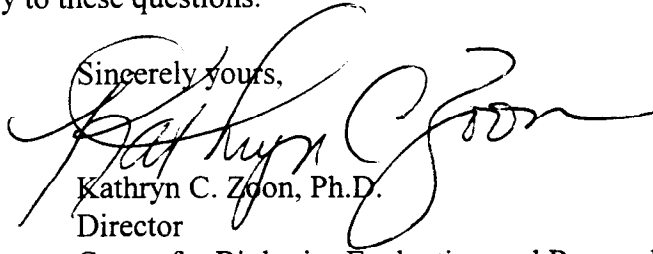
For each licensed product for injection or investigational product for injection used under IND in which any human blood-derived material is used in any stage of manufacture or formulation, or in a diluent, please submit to your application file, within 30 days, information responding to the following points or a statement that no such material was used in the product and an answer to point number four:

- 1) Please describe at what step(s) (e.g. cell lines, fermentation, purification, formulation) blood-derived materials are used in manufacturing or the use of your product and the likely impact of down-stream processing on potential risk of CJD infectivity in the final product.
- 2) Were any products manufactured by your establishment which used any of the withdrawn lots of materials?
- 3) If so,
 - a) If you received a withdrawal notice, which lots of the withdrawn materials did you receive and what actions were taken for products manufactured with this material?
 - b) If products were manufactured with material on the list, what are the lot numbers and final disposition of those products?
 - c) If no notice was received, which lots of materials on the list were used, and what actions are you taking for products manufactured with this material?
 - d) If in the future you incorporate such products into your process, please submit product lot numbers to your license or IND file.
 - e) Are you considering replacement of plasma derived ingredients, and if so, 1) what are they and 2) in what time period do you anticipate replacement?
- 4) If no products were manufactured using these withdrawn lots, what plans or procedures do you have for dealing with any product you make using a blood-derived material if it is withdrawn in the future?

In order to fully answer the above questions, please contact your suppliers of culture media and other raw materials to determine if any of the withdrawn blood-derived products were used in the manufacture of those materials. Questions concerning this letter should be addressed to the application division of the appropriate product office. [For the Office of Blood Research and Review call (301) 827-3524; Office of Vaccines Research and Review call (301) 827-3070; Office of Therapeutics Research and Review call (301) 827-5636.]

Thank you for your prompt reply to these questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Kathryn C. Zoon', written in a cursive style.

Kathryn C. Zoon, Ph.D.

Director

Center for Biologics Evaluation and Research

Attachment

WITHDRAWN HUMAN BLOOD DERIVED MATERIALS DUE TO THE
POSSIBILITY OF THE TRANSMISSION OF CREUTZFELDT-JAKOB DISEASE

Manufacturer: Hyland Division of Baxter Healthcare Corporation, Glendale, CA

Albumin (Human), 5%:

29244212	29244213	29244214	29244218	29244224	29244225
29244226	29244256	29244257	29244258	29244260	29244261
29244262	29244108AA	29242162AA	29243231AA	29243172AA	29243232AA
29243208AA	29243209AA	29242161AA	29243233AA	29243207AA	29243173AA
29242160AA	29243171AA	28212367AA	29244148AA	29243138AA	29244147AA
29243140AA	29243139AA	29244149AA	28211302AA	28211303AA	28211304AA
28212210AA	28212211AA	28212212AA	28212233AA	28212234AA	28212235AA
28212270AA	28212271AA	28212273AA	28212277AA	28212278AA	28212279AA
28212280AA	28212281AA	28212282AA	28212283AA	28212284AA	28212285AA
28212306AA	28212307AA	28212308AA	28212312AA	28212313AA	28212314AA
28212337AA	28212338AA	28212339AA	28212340AA	28212341AA	28212342AA
28212343AA	28212344AA	28212345AA	28212346AA	28212347AA	28212348AA
28212355AA	28212365AA	28212366AA	28893101AA	28893102AA	29244109AA
29244110AA	28212260AA	28212261AA	28212262AA	28212331AA	28212332AA
28212333AA	28212297AA	28212292AA	28212293AA	28212294AA	28212296AA
28212295AA	29243228AA	29243230AA	29243229AA	29244116AA	29244117AA
29244118AA	29244119AA	29244120AA	29244124AA	2924A257AB	2924A258AA
28212330AA	28212359AA	28212360AA	28212361AA	29243109AA	29243110AA
29243111AA	29243131AA	29243132AA	28212328AA	28212329AA	28212331AA
28212332AA	28212333AA	29243125AA	29243126AA	29243130AA	29245242AA
29245243AA	29245244AA	29245236AA	29245237AA	29245238AA	2924C113AA
2924C114AA	2924C115AA	29245255AA	29245256AA	29245257AA	29244125AA
29244218AA	29244219AA	29244220AA	29244313AA	29244314AA	29244315AA
29244221AA	29244222AA	29244223AA	29246131AA	29246133AA	29246134AA
29246135AA	29243252AA	29243253AA	29243254AA	29244290AA	29244291AA
29244292AA	29246241AA	29246242AA	29246243AA	29246244AA	29246245AA
29246246AA	2924D148AA	2924D149AA	2924D150AA	2924D154AA	2924D155AA
2924D156AA	2924D182AA	2924D183AA	2924D184AA	2924D218AA	2924D219AA
2924D220AA	29246158AA	29246159AA	29246160AB	29246155AA	29246156AA
29246157AA	28212365AA	28212366AA	29243115AA	29246291AA	29246292AA
29246293AA	29246297AA	29246298AA	29246299AA	2924C289AA	2924D203AA
2924D204AA	2924D205AA	2889E501AA	2889E502AA	29247124AA	29247125AA
29247126AA	29246173AA	29246173AB	29245145AA	29245146AA	29245147AA
29245284AA	29244237AA	29244238AA	29244239AA	29246263AA	29246236AA
29246237AA	29246241AA	29246242AA	29246243AA	29244280AA	29244281AA
29244282AA	29245180AA	29245181AA	29246257AA	29246257AB	29244283AA
29244284AA	29244285AA	29245222AA	29245223AA	29245224AA	29245288AA
29245289AA	29245290AA	29246253AA	29246254AA	2924C310AA	2924C311AA

2924C312AA 2924D191AA 2924D192AA 2924D193AA 2924E128AA 2924E129AA
2924E130AA

Albumin (Human), 20%:

2806D328AA 2806D310AA 2806D317AA 2806D322AA 2806D308AA

Albumin (Human), 25%:

28374243 28374280 28374288 28374289 28374291 28374311
28374215AA 28374244AA 28373212AA 28373216AA 28373232AA 28372345AA
28373235AA 28372346AA 28373213AA 28373268AA 28374240AA 28373271AA
28373326AA 28373338AA 28374243AA 28374213AA 28374290AA 28331213AA
28332203AA 28332205AA 28332206AA 28332207AA 28371283AA 28371284AA
28371286AA 28371287AA 28371300AA 28372214AA 28372215AA 28372216AA
28372229AA 28372298AA 28372325AA 28372328AA 28372332AA 28372349AA
28373290AA 28373305AA 28373317AA 28374292AA 2837X319BA 2837A311AA
2837A347AA 28373218AA 28373221AA 28373326AA 28373313AA 28373314AA
28374252AA 2837C343AA 2837A331AA 2837A332AB 28372338AA 28372339AA
28333102AA 28333103AA 28373225AA 28373210AA 28373326AA 28375276AA
2837C216AA 2837C217AA 2837C217BA 28375283AA 28375293AA 28375298AA
28374283AA 28375238AA 28375253AA 28374221AA 28374252AA 28374284AA
28374348AA 28374351AA 28373326AA 28374332AA 28375238AA 28375253AA
28373329AA 28374331AA 2837D282AA 2837D003AA 2837D242AA 2837D243AA
2837D262AA 2837D266AA 28376233AB 28372349AA 2837E203AA 2837C324AA
2837D295AA 28376325AB 2837C334AA 2837D257AA 28377213AA 28376242AA
28376266AA 28376272AA 28375218AA 28375306AA 28374301AA 28375308AA
28374298AA 28376313AA 28375219AA 28374310AA 28374309AA 28376271AB
28376257AA 28376288AA 28376236AB 28374325AA 28375241AA 28376285AA
28376296AA 28376326AA 28375244AA 28375265AA 28375271AA 28375315AA
28376282AB 2837E214AA 2824D001AA 2837C340AA 2837C352AA 2837D245AA

Immune Globulin Intravenous (Human), Solvent Detergent Treated:

22054103 26204025 26204043 26204060 26204071 26204083
26204084 26204015 26204016 26204017 26204020 26204024
26204046 26204054 26204058 26204062 26204063 26204067
26204070 26204073 26204074 26204081 26204086 26204088
26204096 26204009 26204012 26204057 26204064 26204014AA
26204033AA 2620D079AA 2620D081AA 22055108AA 2205109AA 26204091AA
26204091BA 26204102AA 26204102BA 26204117AA 26204117BA 26204120AA
26205001AA 26205002AA 26205003AA 26205004AA 26205022AA 26205022AB
26205063AA 26204089AA 26204092AA 26204097AA 26204100AA 26204103AA
26204107AA 26204108AA 26204112AA 26204113AA 26204114AA 26204115AA
26204118AA 26204123AA 26205005AA 26205006AA 26205009AA 26205010AA

26205011AA 26205014AA 26205025AA 26205028AA 26205031AA 26205041AA
 26205049AA 26205059AA 26205062AA 26205014AA 26205017AA 26205025AA
 26205031AA 26205032AA 26205041AA 26205022AB 2620E047AA 2620D079AA
 2620D082AA 2620D084AA 2620D087AA 2620D087AB 2620D087A 2620D088A
 2620D089A 2620D111AA 2620D111AB 2620E043AA 26206054AA 2620D037AA
 2620D053AA 2620D078AA 2620E064AA 26205096AA 26205097AA 26205105AA
 26205093AA 26205094AA 26205095AA 26205098AA 26205099AA 26205103AA
 26205107AA 26205109AA 26205095AA 26205098AA 26205103AA 26205109AA
 26205110AA 26205112AA 26205096AA 26206003AA 26206055AA 26205116AA
 26206094AA 26206094BA 2620E018AA 2620E070AA

Antihemophilic Factor (Human), Method M, Monoclonal Antibody Purified:

2935C075AA 2935C010AA 2935C011AA 2935D065AA 2935D066AA 2935D067AA
 2935D021AA 2935D022AA 2935D035AA 2935D036AA 2935D037AA 2935D089AA
 2935D090AA 2935E020AA 2935E021AA 29355073AA 29355074AA 29356040AA
 29356001AA 29356002AA 29356031AA 29356009AA 29356078AA

Antihemophilic Factor (Human), Method M, Solvent Detergent Treated:

29353090 29353100 29354005 29354024 29354045 29354059
 29354063 29354082 29353089 29353099 29354004 29354023
 29354058 29354062 29354071 29354081 29354092 29353097
 29352261AA 29353046AA 29353073AA 29353098AA 29353052AA 29353028AA
 29353014AA 29352276AA 29353045AA 29352260AA 29353072AA 29353051AA
 29353027AA 29353013AA 29352281AA 29353014AA 29353019AA 29353020AA
 29353085AA 29353086AA 29354012AA 29354013AA 29354108AA 29354116AA
 29354102AA 29354117AA 29354097AA 29354101AA 29354115AA 29354107AA
 29354091AA 29354076AA 29354101AA 29354102AA 29356032AA

Plasma Protein Fraction (Human):

28364486 28364487 28364488 2836522AA 28363524AA 28363523AA
 28363525AA 28363431AA 28363470AA 28363521AA 28363429AA 28363471AA
 28363526AA 28360332AA 28360333AA 28360339AA 28360340AA 28360369AA
 28360370AA 28360448AA 28360450AA 28360482AA 28360483AA 28360484AA
 28361311AA 28361312AA 28361313AA 28361354AA 28361355AA 28361356AA
 28361366AA 28362333AA 28362334AA 28362335AA 28362336AA 28362337AA
 28362338AA 28362379AA 28362380AA 28362381AA 28362384AA 28362385AA
 28362386AA 28363430AA 28361380AA 28361381AA 28361382AA 28362400AA
 28362401AA 28362402AA 28362403AA 28362404AA 28362412AA 28363416AA
 28363417AA 28363418AA 28362426AA 28362427AA 28362428AA 28363422AA
 28364480AA 28362403AA 28362404AA 28362412AA 28364481AA 28364485AA
 28365470AA 28362345AA 28362346AA 28362347AA 28362432AA 28362433AA
 28362438AA 28363507AA 28363508AA 28363509AA 28365470AA 2937D478AA

2937D479AA 2836D480AA 2836D490AA 2836D508AA 2836D509AA 2836D424AA
 2836D425AA 2869D426AA 28362442AA 28362443AA 28362444AA 2836C525AA
 2836C526AA 2836D460AA 2836D541AA 2836D542AA 28367413AA 28367417AA
 28367420AA 28365421AA 28365422AA 28365423AA 28365527AA 28365528AA
 28364503AA 28364504AA 28364505AA 28366491AA 28366492AA 28366493AB
 28366430AA 28364522AA 28364522BA 28364523AA 28364524AA 28365493AA
 28365537AA 28365535AA 28365536AA

Fraction IV-1 Paste:

26283053 26283054 26283055 26283056 26283057 26283099
 26283100 26283101 26283102 26283103 26283197 26283198
 26283199 26283200 26283201 26283202 26284001 26284002
 26284003 26284004 26284005 26284006 26284200 26284201
 26284202 26284203 26284204 2949X022A 2949X023A 2628C011AA
 2628C012AA 2628C013AA 2628C014AA 2628D170AA 2628D171AA 2628D172AA
 2628D173AA 2628D174AA 2628D042AA 2628D043AA 2628D044AA 2628D045AA
 2628D046AA 2628D075AA 2628D076AA 2628D077AA 2628D078AA 2628D079AA
 2628D138AA 2628D139AA 2628D140AA 2628D141AA 2628C147AA 2628C148AA
 2628C149AA 2628C150AA 2628C151AA 2628C152AA 26286198AA 26286199AA
 26286200AA 26286201AA 26286202AA 2628C283AA 2628C284AA 2628C285AA
 2628C286AA 2628D114AA 2628D115AA 2628D116AA 2628D117AA 26283242AA
 26283243AA 26283244AA 26283245AA 26283246AA 26283247AA 26287001AA
 26287002AA 26287003AA 26287004AA 26287005AA 26286079AA 26286080AA
 26286081AA 26286082AA 26286083AA 26285026AA 26285027AA 26285028AA
 26285029AA 26285030AA 26285031AA 26285232AA 26285233AA 26285234AA
 26285235AA 26285236AA 26284214AA 26284215AA 26284216AA 26284218AA
 26284219AA 26286129AA 26286130AA 26286131AA 26286132AA 26286133AA
 26285179AA 26285180AA 26285181AA 26285182AA 26285183AA 26284328AA
 26284329AA 26284330AA 26284331AA 26284332AA 26285232AA 26285233AA
 26285234AA 26285235AA 26285236AA 26283022AA 26283023AA 26283024AA
 26283025AA 26283026AA 26283027AA 26286045AA 26286046AA 26286047AA
 26286048AA 26286049AA 26285070AA 26285071AA 26285072AA 26285073AA
 26285074AA 26285142AA 26285143AA 26285144AA 26285145AA 26285146AA
 26285242AA 26285243AA 26285244AA 26285245AA 26285246AA 26285247AA
 26286149AA 26286150AA 26286152AA 26286153AA 26283098AA 2628A086AA
 2628A087AA 2628C168AA 2628C169AA 2628C170AA 2628C171AA 2628C212AA
 2628C280AA 2628C281AA 2628C282AA 2628C327AA 2628D080AA 2628D081AA
 2628D082AA 2628D083AA 2628D084AA

Fraction I+II+III Paste:

05310199AA 05310204AA 05310212AA 05310261AA 05310262AA 05310226AA
 05310227AA 05310228AA 05310229AA 05310230AA 05313118AA 05313134AA
 05313162AA 05313163AA 05317151AA 05317150AA 05317152AA 05318007AB

05318008AB 05318009AB 05318010AB 05318050AB 05318051AB 05318052AB
 05318053AB 05318054AB 05318267AB 05318268AB 05318269AB 05318270AB
 05318271AB 05318272AB 05319313AA 05319314AA 05316066AA 05316067AA
 05316068AA 05316069AA 05316070AA 05316023AA 05313124AA 05313125AA
 05313156AA 05313143AA 05315015AA 05315016AA 05315049AA 05315050AA
 05315051AA 05315052AA 05315053AA 05315092AA 05315093AA 05315094AA
 05315095AA 05315096AA 05313111AA

Fraction IV-4 Paste:

2796X559A 2796X560A 2796C024AA 2796C025AA 2796C026AA 2796C027AA
 2796D191AA 2796D192AA 2796D057AA 2796D058AA 2796D059AA 2796D060AA
 2796D061AA 2796D115AA 2796D116AA 2796D158AA 2796D159AA 27962167AA
 27962168AA 27962169AA 27962666AA 27962679AA 27962680AA 27962681AA
 27962682AA 27962683AA 2796C232AA 2796C233AA 2796C234AA 2796C235AA
 2796C236AA 2796C237AA 2796C469AA 2796C470AA 2796C471AA 2796C472AA
 2796D145AA 27963562AA 27963566AA 27963567AA 27965045AA 27965046AA
 27965047AA 27965244AA 27965245AA 27964364AA 27964365AA 27964366AA
 27964367AA 27964368AA 27964369AA 27962403AA 27962404AA 27962405AA
 27962406AA 27962407AA 27962408AA 27965198AA 27965199AA 27965244AA
 27965245AA 27963183AA 27963184AA 27963185AA 27963186AA 27963187AA
 27963188AA 27962616AA 27962617AA 27962618AA 27962619AA 27962620AA
 27962121AA 27962122AA 27962522AA 27962523AA 27962524AA 27962525AA
 27962526AA 27963087AA 27963088AA 27963089AA 27963090AA 27963091AA
 27964120AA 27964121AA 27965113AA 27965114AA 27965162AA 27965163AA
 27965255AA 27965257AA 2796A275AA 2796A276AA 2796A480AA 2796A481AA
 2796A482AA 2796A483AA 2796C288AA 2796C289AA 2796C290AA 2796C291AA
 2796C519AA 2796C520AA 2796D117AA 2796D118AA 70203138

Fibrin Sealant:

2655D002AA

TFC:

2944D005

Manufacturer: Melville Biologics, Inc., Melville, NYAlbumin (Human):

S1R42A	S3R95A	S1R09B	S1R91D	S1P75A	S3P62A
S3P65A	S1P96D	S1P97C	S1P97D	S2R91A	S2P44B
S1R91B	K1R09A	S2P39B	S2P39A	S3R71A	

Fraction II+III Paste:

1R42	1R09	1P22	3P07	1N37	1N22	2N17	1P09	2P39	1M40	3P21	1P17
3N40	2P44	2P38	1E21	2N23	1N28	3P25	1M38	3N29	1N38	1N19	

Plasma Cryoprecipitate:

1R42	1R09	3P07	1N37	1N22	2N17	1P09	1R42	1N37	1N22	2N17
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Plasma Protein Fraction (Human):

K1R09A	K2P38A	K2P38B	K2P44A
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Antihemophilic Factor (Human):

1P22

Manufacturer: Bayer Corporation, Clayton, NCAlbumin (Human), 25%:

684N042 684N043 684N047 684P005

Fraction IV-4 Paste:

611V002 N906P004

Immune Globulin Intravenous (Human):

649N094

Alpha-1-Proteinase Inhibitor (Human), Prolastin:

01Y002	01Y019	01Y028	601N067	601P014	601P033
601P044	601P048	601P028	601P032	601P074	601R019
601R023	601R032	601N076	601N078	601N079	601N078A
601P066	601P073	601P090	601P027	601P037	601P051
601R034	601R041	601R073	601R084	601R094	601S005
601S013	601P080	601R010	601R017	601S052	601S078

Manufacturer: Bayer Corporation, Kankakee, IL

Human Transferrin, Iron Poor (APO):

126

Human Transferrin, Partially Iron Saturated:

311 313

Human Transferrin, Iron Saturated (HOLO):

43 44

Manufacturer: Bayer Corporation, Clayton, NC
Distributor: Bayer, Inc., Etobicoke, Ontario, Canada

Plasma Cryoprecipitate:

C8Y008 6C8N002 6C8N006 6C8P002 6C8P002Y 6C8P003

Albumin (Human), 5%:

6C5P001A 6C5N006B 6C5P003 6C5P001B 6C5P004B 6C5N001
6C5N005

Albumin (Human), 25%:

6C4N019A C4Y002 C4Y003 C4Y015 C4Y016 6C4N003
6C4N004 6C4N005 6C4N006 6C4N018 6C4N019B 6C4N020
6C4P008 6C4P001 6C4P002 C4X029 C4X031

Immune Globulin Intravenous (Human):

6C2N018A 6C2P001A 6C2N002A 6C2N002B 6C2N004 6C2N018B
6C2P001B 6C2N022 C2X010 C2X018

**Manufacturer: Central Laboratory Blood Transfusion Service Swiss Red Cross,
Bern, Switzerland**

Albumin (Human), 25%:

1.270.045.0	5.271.023.0	5.271.123.0	5.271.105.0	6.280.030.0	6.270.201.0
6.280.203.0	5.270.046.0	5.280.004.0	5.280.047.0	5.280.073.0	6.280.001.0
5.280.019.0	5.280.020.0	5.270.076.0	5.260.061.0	5.260.125.0	5.270.126.0
6.280.036.0	6.270.260.0	6.270.013.0	6.270.041.0	6.280.017.0	6.280.046.0
6.280.262.0	6.280.280.0	6.280.283.0	5.271.012.0	6.271.254.0	

Immune Globulin Intravenous (Human), Sandoglobulin:

2.370.355.0	2.370.356.0	3.370.234.0	3.370.235.0	3.363.255.0	3.363.290.0
3.373.247.0	3.373.248.0	3.373.254.0	3.373.280.0	3.373.281.0	3.373.287.0
4.373.279.0	4.373.280.0	4.373.291.0	4.373.292.0	4.373.298.0	4.373.299.0
4.373.301.0	4.373.302.0	4.373.307.0	4.373.313.0	4.373.327.0	4.373.328.0
4.374.354.0	4.374.355.0	4.374.364.0	4.374.365.0	4.374.409.0	4.374.412.0
4.374.438.0	4.374.439.0	4.374.440.0	4.374.441.0	4.374.452.0	4.374.456.0
4.403.261.0	4.403.348.0	4.403.509.0	4.403.510.0	5.364.331.0	5.374.207.0
5.403.296.0	5.403.297.0	5.403.411.0	5.409.476.0	5.409.546.0	6.373.286.0
6.373.287.0	6.373.288.0	6.373.289.0	6.373.290.0	6.373.291.0	6.409.200.0
6.409.261.0	6.371.500.0	6.371.501.0	6.371.513.0	6.373.286.0	6.373.287.0
6.376.288.0	6.373.289.0	6.373.290.0	6.373.291.0	7.403.426.0	6.371.509.0
5.409.434.0	5.409.412.0	5.409.388.0	7.371.444.0	6.379.219.0	6.409.222.0
6.409.223.0	6.409.334.0	7.379.341.0	7.379.342.0	6.403.251.0	6.406.307.0
6.373.446.0	6.373.447.0	6.403.457.0	6.403.536.0	5.403.545.0	5.403.558.0
6.403.233.0	6.406.307.0	7.409.394.0	7.409.554.0		

Fraction I + II + III Paste:

05316043AA 05316044AA 05316045AA 05316046AA 05316047AA 05316023AA

Manufacturer: Alpha Therapeutics Corporation, Los Angeles, CA

Immune Globulin Intravenous (Human):

GL7532A GL7535A GL7536A GR7034A GR7036A

Coagulation Factor IX (Human):

CV7006A CV7013A

Albumin (Human), 5%:

NF7036A NF7037A NF7039A

Albumin (Human), 20%:

NC7511A NC7513A NC7514A

Albumin (Human), 25%:

NB7026A NB7027A NB7030A NB7030AB NB7036A