

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125562/0 Office: OBRR

Product:

Anthrax immune Globulin (Human), AGIV, [ANTHRASIL]

Applicant:

Cangene Corporation [Emergent Biosolutions]

Telecon Date/Time: 19-Mar-2015 09:30 AM Initiated by FDA? Yes

Telephone Number: (b) (4) Passcode: (b) (4)

Communication Category(ies):

1. Advice

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Telecon Summary:

To discuss Cangene's request for Strategic National Stockpile (SNS) labeling exception

FDA Participants:

Robert Fisher, CBER/OBRR

Nicolette Devore, CBER/OD

Cynthia Kelley, CBER/OD

Thomas J. Maruna, CBER/OBRR

Non-FDA Participants:

Cangene

Dr. Tim Babinchak VP Clinical & Medical Affairs, Biodefense Division

Dr. Gurdyal Kalsi VP Clinical & Medical Affairs

Jeannette Rosolowich Senior Director, Project Management

Steve McGregor Director, Regulatory Affairs

Dr. Christine Hall Director, Clinical

Darren Ross Senior Manager, Project Management

Allison Kennedy Manager, Regulatory Affairs

Dr. Bojan Drobic Scientist, Clinical Research

Shelley Toth Specialist, Regulatory Affairs

Jennifer Wagstaff Project Manager

BARDA

Mike Merchlinski

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

The Agency requested a teleconference with Cangene to discuss PMC # 9 for BLA 125562/0:

Cangene commits to submitting a request for exemptions or alternatives to labeling requirements for biological products held by the Strategic National Stockpile per 21 CFR 610.68. This request will include specific lot numbers, the labeling provisions that are the subject of the exemption or alternative request, an explanation why compliance with the labeling regulations could impact the safety, effectiveness, or availability of AIGIV, a description of proposed safeguards to ensure the labeling of the product conveys adequate information for the safe and effective use of the product, and a draft of the proposed labeling. Cangene will submit this information as a CBE30 by April 25, 2015.

It is the Agency's position that the information submitted by Cangene to the BLA justifying a request for a SNS labeling exception for AIGIV is not acceptable per 21 CFR 610.68. The Agency requested Cangene submit to the BLA a revision to the primary vial label for product manufactured post-approval, to include the manufacturing date, in lieu of an expiration date, on new vials of AIGIV to be included in the SNS in the future. The Agency also explained to Cangene the reasons for the requested PMC and what should be included; a protocol detailing how the labeling for product currently in the SNS will be exchanged post-approval, such as the removing of the zipper labels, repackaging in appropriately labeled boxes/cartons, insertion of the PI, time and temperature monitoring of the manufacturing operation and a general timeline regarding completion of these activities for all product in the SNS. Cangene agreed to the revision and protocol submission.

The Agency also suggested Cangene consult with the Centers for Disease Control and Prevention (CDC) concerning the size of vial cartons. Presently the proposed carton size has a capacity for 6 vials; a single dose of AGIV requires 7 vials. It is the Agency's position that a 6-vial carton will not facilitate a public health response in an emergency. The Agency suggested Cangene consider a (b) (4) carton size in consultation with the CDC, and BARDA if necessary. Cangene agreed to consult with CDC regarding the carton size.

END