



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 21-05

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Executive Team

FROM: Byron Rippke
Director

SUBJECT: Supply Chain Disruptions Associated with the COVID-19
Pandemic

I. PURPOSE

This purpose of this notice is to solicit input from the regulated Veterinary Biologics industry to assess the impact of current and anticipated ongoing supply chain disruptions of vital materials used in the manufacturing of veterinary biological products.

II. BACKGROUND

The COVID-19 pandemic has caused and continues to cause problems in manufacturing supply chains in many industry sectors. The necessity of prioritizing critical materials used for treating affected individuals, human diagnostic testing, and human vaccine development and manufacturing has impacted supply chains for materials used in the manufacturing of veterinary biologics. To better understand the possible scope of potential problems, devise possible solutions, and begin consideration of alternatives where appropriate, the Center for Veterinary Biologics (CVB) is requesting veterinary biologics manufacturers share any pertinent information.

III. ACTION (or POLICY)

CVB is requesting veterinary biologics manufacturers provide specific information related to supply chain disruptions of critical materials used to manufacture veterinary biologics, along with information of resulting potential product shortages. Possible solutions to alleviate the impact of shortages, such as the use of alternate materials or alternate sources of materials, may be included. CVB will determine if regulatory flexibility can be used to support proposals for use of alternatives if those alternatives are scientifically justified.

IV. IMPLEMENTATION/ APPLICABILITY

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Please submit relevant information to your Reviewer in a routine submission with the *Brief Submission Description* entry of “SUPPLY CHAIN DISRUPTIONS”. Outline the specific products that are not available, the manufactured veterinary biologics product codes affected, and any available information on the duration of the impact. Include possible solutions for consideration by CVB and supporting scientific justification for the proposal if appropriate. The information will be collected from the entire industry community and may be used to make general statements. However, all information that could be linked to any individual manufacturer and/or product will be treated as confidential business information as with any other submission.