Pharmaceuticals Case Study

Importing Vaccines into the USA prior to the Annual Strain Approval

The Challenge

The Client was importing vaccines into the USA for further processing, filling into syringes, labelling, packing and warehouse storage prior to the U.S. Food and Drug Administration (FDA) annual strain change approval. The Center for Biologics Evaluation and Research (CBER) and the FDA were insisting that the Client complied with two different import processes, which resulted in up to 30 days of production delays. These delays were impacting sales into the U.S. market, due to late release of products following the to the annual strain change approval.

The Solution

I prepared and submitted a detailed argument to challenge the FDA and CBER import requirements, which were contradictory and not in accordance with the regulations stated in the U.S. Federal Register.

The importer is required to make an application for 'Request for Authorization to Relabel or Perform Other Acts' by either letter or by the FDA Form 766 process under the U.S. Code of Federal Regulations Title 21 Food and Drugs, Chapter l, Part 1, Subpart E – Import and Exports. Therefore, as the Client had a CBER response to their letter stating that CBER did not object to the importation of vaccine, there was no requirement to follow the lengthy FDA Form 766 process which delayed production by up to 30 days.

The Results

Further to presentations and detailed discussions, the following statements were issued:

- CBER stated 'For the 2019-2020 Influenza Vaccine Import Requests, we are no longer requesting that importers submit FDA Form 766'.

- The FDA stated 'They did not object to shipments travelling to the consignee under bond for commencement of the activities described in the Import Request accepted by CBER'.

The acceptance of a new fully compliant end-to-end process by the FDA and CBER reduced clearance times, removed unnecessary documentation and administration, and increased sales due to earlier product release to the U.S. market.

Client testimonial

'This is fantastic news and will have a dramatic effect on our throughput compared to the previous couple of years. Well done for driving the request for improvement in this process'.

Global Head of Manufacturing and Operations

If you would like more details, please call +44 (0) 118 932 8447 or email info@icsglobalservices.co.uk

ICS Global Services Limited

http://www.icsglobalservices.co.uk/