



Case Study:

# FTZ SUBZONE FOR API CLEARANCE

## CHALLENGE

A customer needed to change from a domestically sourced API (active pharmaceutical ingredient) to an alternative, foreign-made API for a commercial product while avoiding any disruption to patient supply during the switch.

## APPROACH

JHS established a Foreign Trade Zone (FTZ) subzone with the US government that covered the entire Spokane facility. FTZs can offer many benefits, including faster speed to market, cost savings, logistical flexibility, and inventory control. In this case, the FTZ saved the customer time and money by allowing JHS to continue manufacturing the product while collecting stability data for a future FDA filing on the alternative API source.

## RESULTS

It took JHS about 5 months from start to finish to establish an FTZ subzone, outpacing the national average of 10 months to launch according to the International Trade Administration. Upon approval, JHS began converting the foreign API into a commercial-ready product and worked toward a regulatory filing on an expedited schedule.

## CONCLUSION

FTZ subzones can be a great tool for customers interested in using American manufacturing expertise while expediting regulatory pathways in a cost-effective manner. JHS can now leverage its existing FTZ subzone status to partner with customers interested in its benefits.

## AT A GLANCE



Launched FTZ 5 months earlier than industry average



Maintained uninterrupted supply to patients



Integrated new, foreign-made API into US manufacturing without disruption

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