



IBPE Petition for Waiver


State of Iowa

Submitted On:

August 19, 2020 1:58pm

America/New_York

Licensee/Registrant Name	ALK-Abello, Inc
License/Registration No.:	5124
Address Autocomplete	2 Channel Drive, Port Washington, NY, USA
Contact Person for Petition for Waiver	Ashley Jourdan
Direct Phone Number for Contact Person	5167675705
Direct Email Address for Contact Person	ashley.jourdan@alk.net
List each rule you are requesting to be waived:	657 IAC 17.3(1)“c” requiring evidence of current verified-accredited wholesale distributors (VAWD) accreditation by the NABP
Describe specifically which requirements you are requesting to be waived	Evidence of current VAWD accreditation by NABP
Start Date	9 1 2020
End Date	9 1 2025
Have you previously requested a waiver of any of the rules listed above?	No
If so, what was the outcome?	
Explain why following the rule would pose an undue hardship:	To comply with Iowa's new VAWD accreditation requirements for 2020, ALK has reached out to schedule the first available date for an onsite survey. We were scheduled for March 19,2020, but due to the COVID19 pandemic, NABP postponed the onsite survey. NABP has already reviewed our application documentation and was to review only certain areas during their onsite survey prior to awarding ALK accreditation. As we are still in COVID19 situation, we have been waiting for NABP to reschedule their onsite survey. However, we have been recently notified the survey should be expected but it will take some time to get the results. In the meantime, ALK is unable to sell/ship/distribute PrePen into Iowa under its current Limited Distributor license. ALK is the exclusive distributor of PrePen, which is manufactured by a company other than ALK and there are no other companies that manufacturer or distribute a similar product. ALK is an essential business as supplier of pharmaceutical product and respectfully request a VAWD waiver for the foregoing reasons.
Explain how waiving the rule may impact other people:	The undue hardship is that Iowa residents will not be able to get PrePen and (ii) ALK will not be able to ship/sell PrePen into Iowa.
Explain how the rule is intended to protect the public health,	Making sure that products are accredited prior to being shipped into Iowa. We are in the process of getting VAWD accredited but there has been a significant delay because of COVID19.

safety, or welfare:	
Explain how the public health, safety, or welfare can still be protected if the rule is waived:	This is not a new product that is being sent into Iowa, it has been shipped into Iowa for years. We are in the process of being VAMD accredited.
Have you spoken to a Board compliance officer or other member of Board staff about your request?	Yes
If so, who?	Andrew Funk, Executive Director Iowa Board of Pharmacy
Attach copies of any relevant email correspondence	https://seam.ly/KbFFJ5HI Iowa e-mails.pdf
Do you plan to attend the Board meeting when this Petition will be considered?	No
Signature Data	First Name: Ashley Last Name: Jourdan Email Address: ashley.jourdan@alk.net  Signed at: August 19, 2020 1:58pm America/New_York
Receipt	0000023