

November 12, 2024

Mr. Lance Morgan
President and Chief Executive Officer, Ho-Chunk, Inc.
818 St Augustines Drive
Winnebago, NE 68071
legal@hochunkcorporateservices.com

Re: Docket FDA-2024-P-2461

Dear Mr. Morgan:

This is a tentative response to inform you that the Food and Drug Administration (FDA) does not yet have a final response to your citizen petition dated on May 17, 2024, and submitted on behalf of Rock River Manufacturing Company (“Rock River”).

Your petition requests that FDA issue a regulation to include an exemption for tribally-owned cigarette manufacturers from Part 1120 of proposed FDA-2013-N-0227, “Requirements for Tobacco Product Manufacturing Practice.”

In accordance with Title 21 Code of Federal Regulations Section 10.30(e)(2)(iv), this letter is to advise you that we have not yet reached a decision on your petition within the first 180 days of its receipt because of the issues raised, which require additional review and consideration by the Agency. We will continue to review the issues raised and complete our review of your petition in the context of other program priorities within the Center for Tobacco Products.

Regards,



May D. Nelson
Director, Office of Regulations
Center for Tobacco Products
Food and Drug Administration