



VIA ELECTRONIC SUBMISSION ON REGULATIONS.GOV

Mr. Xavier Becerra, Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201
Xavier.becerra@hhs.gov

Robert Califf, M.D., Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Robert.califf@fda.hhs.gov
commissioner@fda.hhs.gov

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Date: May 17, 2024

The undersigned submits this petition pursuant to Chapter IX of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, 21 C.F.R. § 10.30, Executive Order 13175, and HHS Tribal Consultation Policy to request the Commissioner of Food and Drugs to include a tribal waiver in the Final Rule regarding Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15174 *et seq.*, proposed part 1120 (21 CFR part 1120).

A. ACTION REQUESTED

The undersigned submits this Citizen Petition on behalf of Rock River Manufacturing Company (“Rock River”) to request that the U.S. Department of Health and Human Services (“HHS”) Food and Drug Administration (“FDA”) ISSUE a REGULATION to INCLUDE AN EXEMPTION FOR TRIBALLY-OWNED CIGARETTE MANUFACTURERS FROM PART 1120 OF PROPOSED RULE FDA-2013-N-0227, REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE (“Proposed Rule”).

B. STATEMENT OF GROUNDS

I. Introduction

Ho-Chunk, Inc. (“HCI”) is wholly owned by the Winnebago Tribe of Nebraska (“Tribe” or “Winnebago Tribe”), a federally recognized Indian tribe. Rock River is a wholly owned subsidiary of HCI. HCI and its subsidiaries—including Rock River—are considered arms of the Tribe. Rock River manufactures cigarettes using substantially equivalent products. It manufactures multiple cigarette brands that are made with two primary tobacco blends. Rock River does not manufacture Electronic Nicotine Delivery Systems (“ENDS”) or related products, only cigarettes.

FDA Citizen's Petition
Page 2

In 1999, amidst chronic and severe unemployment, the Winnebago Tribe invested in cigarette manufacturing to bolster the economic development of the Tribe and to create income and jobs for tribal members. Rock River is located on the Winnebago Reservation, where the company currently employs eight people. Today, this economic engine allows the Tribe to both collect revenue by way of a corporate distribution and generate tribal tax revenue that the Tribe collects. The Tribe taxes and regulates every sale of tobacco products sold and manufactured on the Winnebago Reservation as a function of its inherent sovereign regulatory authority.

The purpose of this Citizen Petition is to amend the Proposed Rule to include an exemption for tribally owned cigarette manufacturers, in order to protect tribal economic health consistent with federal policy. As written, the Proposed Rule will dramatically impact the Tribe's ability to continue to manufacture cigarettes, which will in turn harm economic growth on the Winnebago Reservation.

II. Further Regulation of Tribal Tobacco Manufacturers Will Harm Viability of Industry

Due to a number of factors, including regulatory hurdles, Rock River has been operating at a loss since 2016. The Tribe entered into the Universal Tobacco Settlement Agreement with manufacturers, including Rock River. This agreement imposes sizable fees on the signatory manufacturers and distributors and other restrictions regarding tobacco use within the Tribe's jurisdiction, including prohibitions on advertising to minors and requirements that manufacturers pay directly to the Tribe per sale. The payments fund measures that compensate for adverse health effects and exposures on the Winnebago Reservation. Tribal manufacturers and distributors paid \$31,681.00 in fees under this agreement in 2017 alone. Rock River's distributors transport its cigarettes to other federally recognized Indian Tribes and to other states. Rock River has a small but mighty supply chain, and it is dedicated to complying with all laws and regulations within each jurisdiction where its cigarettes are distributed. Unfortunately, due to restrictive changes in regulations over the last few years, Rock River has been unable to maintain other tobacco products it once sold such as pipe tobacco, and cigars.

If finalized, the entirety of the Proposed Rule will cost Rock River a substantial amount to implement, therefore, costing the Tribe time and money. More time will be spent doing paperwork than is currently spent running Rock River's manufacturing lines. Whether it's additional record keeping requirements for the company and its personnel, investigating frivolous non-user complaints, implementing additional facility controls, or sampling and testing cigarettes, Rock River will struggle to fund these many changes.

The FDA's proposed rule would provide an "umbrella" procedural framework for product manufacturers of all types of finished and bulk tobacco products. Proposed Rule at 15183. Major elements of the proposed rule include:

- 1) Establishing product design and development controls.
- 2) Ensuring that manufacture conforms with established specifications.
- 3) Minimizing the likelihood of the manufacture and distribution of nonconforming products.
- 4) Requiring investigation and identification of products, including those that have distributed, to enable manufacturers to institute appropriate corrective actions.
- 5) Requiring manufacturers to take appropriate measures to prevent contamination of tobacco products.
- 6) Establishing traceability to account for all components or parts, ingredients, additive, and materials, as well as each batch of finished or bulk tobacco product.

FDA Citizen's Petition

Page 3

The Proposed Rule in its Preliminary Economic Analysis of Impacts indicates “(t)he Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities are likely to incur a large portion of the costs to comply with the proposed rule, we find that the proposed rule would have a significant economic impact on a substantial number of small entities.” Proposed Rule at 15239. That impact, in the case of Rock River, is the potential for the company to fail.

III. Conclusion

Rock River is one of only two tribally-owned tobacco product manufacturers in the United States. The limited scope of the requested exemption would only have a minimal impact on the whole market. Furthermore, Rock River only manufactures cigarettes, which are already highly regulated, unlike ENDS and other similar products. Allowing an exemption from part 1120 of the Proposed Rule will allow this tribally-owned economic development company to survive and continue to provide jobs and resources to the Tribe.

C. ENVIRONMENTAL IMPACT

The action requested in this petition will not have any significant effect on the quality of the human environment.



D. ECONOMIC IMPACT

The economic impact statement will be submitted upon request of the Commissioner.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

DocuSigned by:

By: 
Lance Morgan
President and Chief Executive Officer, Ho-Chunk, Inc.
818 St Augustines Drive
Winnebago, NE 68071
(402) 878-2809