U.S. FOOD & DRUG ADMINISTRATION

October 16, 2017

Michael A. Carome, M.D.
Public Citizen Health Research Group
1600 20th Street NW
Washington, D.C. 20009

Re: Citizen Petition – Docket Number FDA-2011-P-0331

Dear Dr. Carome:

The Food and Drug Administration (FDA) has completed its review of your citizen petitions filed on May 2, 2011, and assigned Docket Number FDA-2011-P-0331. In this petition, you made two requests: (a) to ban on the use of cornstarch powder on all surgeon's and patient examination gloves, and (b) to ban on the use of all natural rubber latex (NRL) surgeon's and patient examination gloves. We have considered your petition, and we are granting it in part and denying it in part.

I. Petition to Ban Powdered Gloves

Your petition requests that FDA ban the use of cornstarch powder on surgeon's and patient examination gloves. Your petition and the information that you provided with your petition was considered as part of the basis for FDA's proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove (81 FR 15173 at 15175-76, March 22, 2016). On December 19, 2016, FDA issued a final rule banning powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove (81 FR 91722) (the "final rule"). The full rationale and basis for our decision can be found at the Federal Register citations provided in this paragraph. Therefore, per the final rule, we have granted this request in your petition.

II. Request to Ban Natural Rubber Latex (NRL)

Your petition also requests that FDA ban the use of NRL surgeon's and patient examination gloves. We deny this part of your petition.

As we discussed in the preamble to the final rule, FDA finds that the risk of allergic reaction to non-powdered NRL gloves, which affects the user and patients in direct contact with the glove, is adequately mitigated through already-required labeling that alerts users to this risk. NRL gloves must include a statement to alert users to the risk of allergic reactions caused by NRL. We also noted in the preamble to the final rule that several studies have indicated that the use of non-powdered NRL gloves reduces the risk of sensitization to allerginec NRL proteins and the number of allergic reactions experienced by those who are already sensitized. FDA believes that these study results, when considered alongside the risk mitigation that follows from FDA's

required labeling for NRL products, demonstrate that non-powdered latex gloves can be safely used with appropriate caution for latex-sensitive patients and health care workers. Therefore, FDA decided not to ban NRL products. For these reasons, we deny this part of your petition.

III. Conclusion

As discussed above, after consideration of your petition and other supporting evidence, FDA has issued a final rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove (81 FR 91722). For this reason, FDA considers your request to ban the use of cornstarch powder on all surgeon's and patient examination gloves to have been granted. However, for the reasons discussed above and described in more detail in FDA's proposed and final rule, FDA is denying your petition's request for FDA to ban all natural rubber latex gloves. If you have any questions about this response, please contact Erica Payne of our Regulations Staff at 301-796-3999.

Sincerely yours,

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration