Non-pharmaceutical grade component, (b)(4), is used in the formulations of non-sterile drug products, i.e. topical creams used to treat severe muscular pain. Specifically, your firm used (b)(4) to produce approximately (b)(4) prescriptions made in non-sterile drug production from 2012 to 2019. For example:

A. Ketoprofen 5% Gel was prepared using (b)(4) for a total of (b)(4) times from 2012 to 2019.

B. (b)(4) base, (b)(4), is used as a component in over (b)(4) different non-sterile drug formulas. Your firm prepared (b)(4) using (b)(4) in (b)(4) prescriptions from 2012 to 2019.

C. From 2013 to 2019, your firm formulated (b)(4) prescriptions of a cream, Ultracaine-Benzocaine 20%, Lidocaine 8%, Tetracaine 4%, Ibuprofen 2%, Bupivacaine 0.5%, that used (b)(4).

There is no evidence that (b)(4) used to produce creams and liquid non-sterile drug products is of an appropriate quality for its intended use.

*Dates of the Inspection: 02/07/2019, 02/11/2019, 02/12/2019, and 02/14/2019