COLORADO
Department of Health Care Policy & Financing

1570 Grant Street
Denver, CO 80203

March 23, 2023

Ms. Leigh Verbois
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services
1001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

RE: Intent to Respond to FDA's Request for Information

Dear Ms. Verbois:

Please accept this letter as Colorado's formal intent to respond to the FDA's Request for Information (RFI), as shared during our meeting with the FDA on March 2. Our intention is to address the requested information within our Section 804 Importation Program (SIP) submitted on December 5, 2022 and submit a formal response as soon as feasible.

As discussed at our meeting on March 2, we would like to explore creative strategies to address a specific challenge for state-led importation programs. As you know, Colorado must negotiate with drug manufacturers to secure supply for our program. It has been made clear that potential partners will be more interested in committing to participate once our program has been approved by the FDA. While we understand the regulatory framework does not permit for a provisional approval, we know that showing progress towards an approved program will aid in our negotiations with drug manufacturers. We would like to discuss this further with you in an upcoming meeting to be scheduled at your convenience, as well as other process related questions, outlined below.

- Should the State of Colorado expect additional RFIs? If yes, will these build on the content included in the RFI dated March 2nd or should we expect other RFIs covering other aspects of the application outside the scope of that letter?
- Once the responses to all RFI requests have been submitted, what is the timeline for a final review of these outstanding items?

In reviewing the RFI, we identified two different categories of requests. The first, which we refer to as short term, are in process or completed as of submission of this letter. The

detailed changes will be included in our updated SIP application to be submitted at a later date.

Short Term Requests

- 251.3(d)(10): Adequate evidence of registration for the relabeler
- 251.3(e)(14): Disposition of non-saleable products
- 251.9(a): Foreign Seller registration
- 251.3(e)(11)(i): Special storage conditions
- Port Entry changed to Detroit, MI

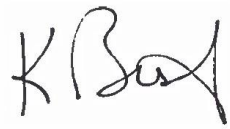
The second category is requests that are longer term, require significantly more time to address, and in most cases are dependent upon the outcome of our negotiations with drug manufacturers. We cannot assess the exact timeframe for responses to these items, but below is a summary of the long term requests.

Long Term Requests

- 251.3(d)(5): Name and address of manufacturer of finished dosage form of each eligible prescription drug on the Drug List.
- 251.3(d)(6): Name and address of the manufacturer of the active ingredient or ingredients of the eligible prescription drugs.
- 251.3(e)(1): Name and address of manufacturer of finished dosage form of each eligible prescription drug on the Drug List.
- 251.3(e)(6): Provide adequate evidence that each HPFB-approved drug's FDA-approved counterpart drug is currently commercially marketed in the United States.
- 251.3(e)(15)(vi): Include the adoption of processes and procedures for uncovering and addressing conflicts of interest.

We look forward to additional engagement on these matters. Should the FDA have any questions during the review process, please contact Lauren Reveley, Colorado Department of Health Care Policy & Financing Drug Importation Program Manager, at Lauren.Reveley@state.co.us.

Sincerely,



Kim Bimestefer
Executive Director
Colorado Department of Health Care Policy & Financing