

Update regarding NDA filing for Sofpironium Bromide

26 September 2023

Presenters



VINCE IPPOLITO

Executive Chairman

- COO of Anacor and Medicis; former President Dermavant; more than 17 years at Novartis.
- More than 35 years experience in pharma with 20+ years within dermatology



HOWIE MCKIBBIN

Chief Executive Officer

- Former SVP Commercial of Dermavant, Anacor and Medicis
- 20+ years working in dermatology - launched more than 15 brands and managed over 35 dermatology products



DR PATRICIA WALKER

Chief Medical Adviser

- Former President and head R&D Brickell Biotech
- Former CMO/CSO Kythera, Inamed and Allergan Medical responsible for multiple drugs incl. Botox and Tazorac



MATT CALLAHAN

Board Executive Director

- Serial founder and ex-investment director of two venture capital firms in life sciences
- Developed four products through FDA approval and launch



Dave Clissold

Director

Hyman, Phelps & McNamara

Mr Clissold has broad-based experience advising pharmaceutical, biotechnology, medical device, food, and dietary supplement clients on regulatory and legislative matters at HPM. HPM is the largest dedicated FDA law firm in the United States

Mr Clissold provides guidance throughout the product lifecycle, which includes clinical trials and drug development, advertising and promotion, orphan drug designations, and Hatch-Waxman exclusivity.

Mr Clissold lectures on various FDA topics, including regulation of tobacco products, regulatory obligations in clinical investigations, strategies for developing and marketing drugs and biologics, orphan drugs, and Hatch-Waxman issues. He has presented to the Food and Drug Law Institute and has published papers in *The New England Journal of Medicine*, *The Journal of Pharmacology and Experimental Therapeutics*, *Pharmacology, Biochemistry & Behavior*, and the *Food and Drug Law Journal*.

Announcement today

Botanix receives Letter from FDA identifying one area for clarification relating to patient use instructions

- ❖ The **only** area listed in the Letter was **related to the how the patient is instructed to use the product, including the printed Instructions for Use document**
- ❖ **No clinical efficacy, safety, pharmacology, non-clinical or manufacturing issues were raised and no additional clinical studies are required by FDA to support NDA approval**
- ❖ **No new review issues are anticipated as part of the resubmission review and the requested activities can be quickly addressed - approval pathway further de-risked**
- ❖ **Botanix will meet with FDA and undertake the minor activities and plans to resubmit the NDA by early Q1 CY2024, with a target approval of mid-CY2024**
- ❖ The Company is **well funded to complete the resubmission with an anticipated delay in launch from 1Q CY2024 of 3-6 months, with no change in large market opportunity**

'Complete Response Letter' and 'End of Review' meeting

- ❖ A Complete Response Letter communicates to a sponsor that the FDA cannot approve the application in its present form and describes any areas that must be addressed before the application can be approved¹
- ❖ The sponsor is not provided with a prior copy of the Complete Response Letter and does not have the opportunity to communicate freely with FDA outside the standard meeting schedule (e.g mid-cycle etc) and the formal meeting request process (e.g Type B meeting – 60 days prior notice)
- ❖ FDA regulations do offer an End-of-Review meeting, which is attended by senior FDA personnel and following request, FDA has 30 days to grant and hold that meeting

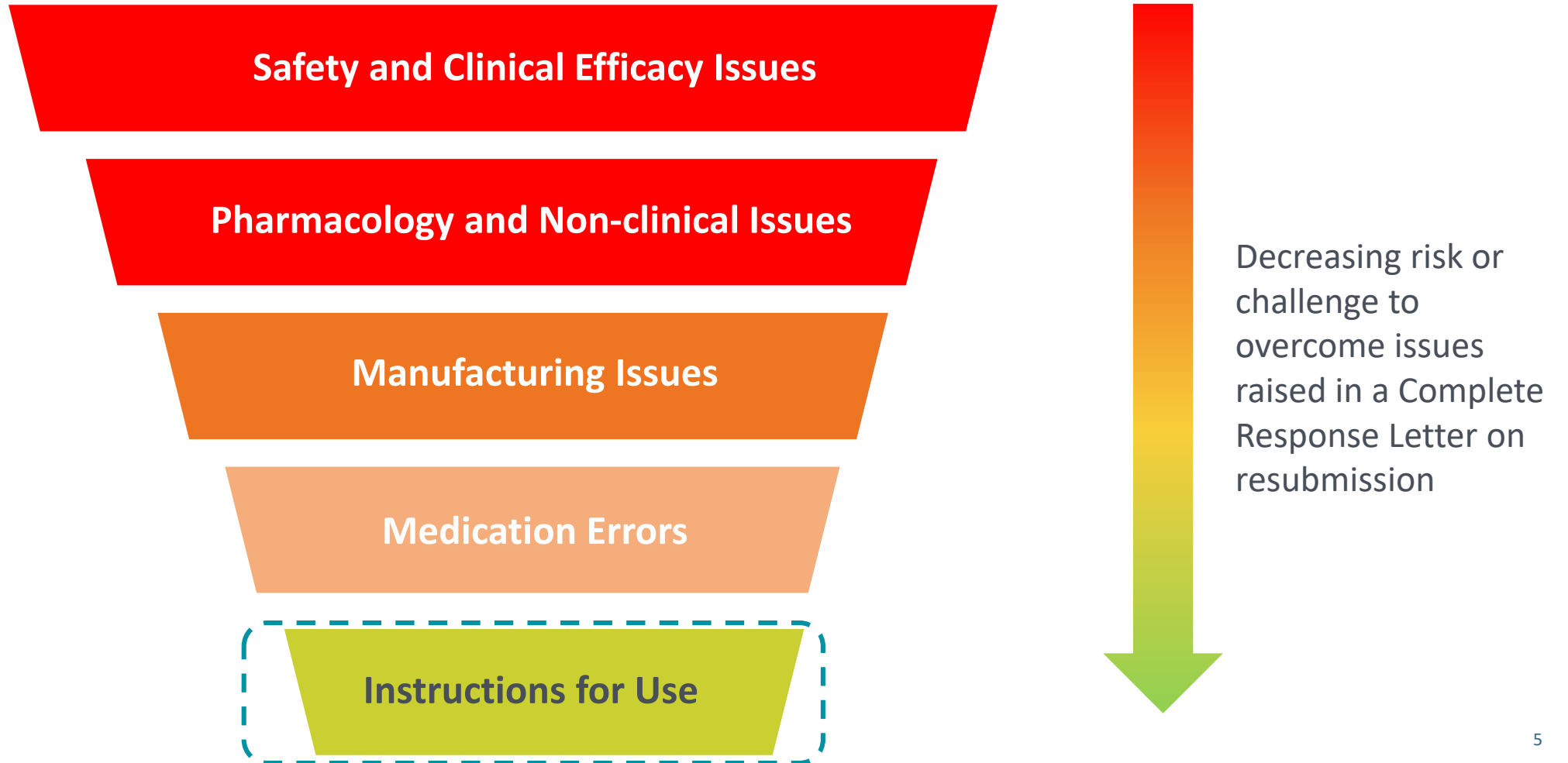
(1) *Description of specific deficiencies.* A complete response letter will describe all of the specific deficiencies that the agency has identified in an application or abbreviated application, except as stated in paragraph (a) (3) of this section.

(2) *Complete review of data.* A complete response letter reflects FDA's complete review of the data submitted in an original application or abbreviated application (or, where appropriate, a resubmission) and any amendments that the agency has reviewed. The complete response letter will identify any amendments that the agency has not yet reviewed.

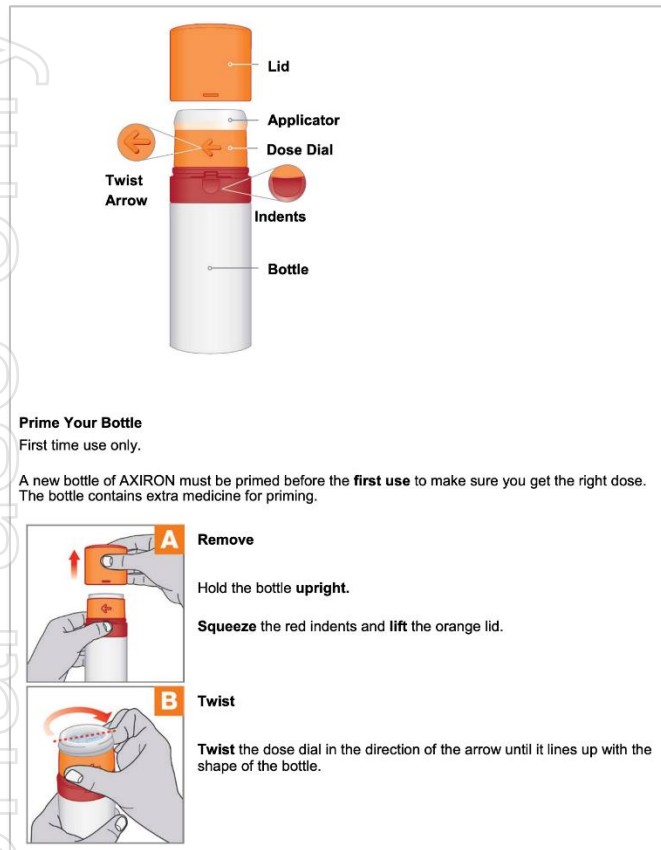
1. 21CFR314.110 – Part 314 – Applications for FDA approval to Market a New Drug

Issues that could be raised in a Complete Response Letter

No safety, efficacy, pharmacology, non-clinical or manufacturing issues were raised in the letter for Sofpironium Bromide



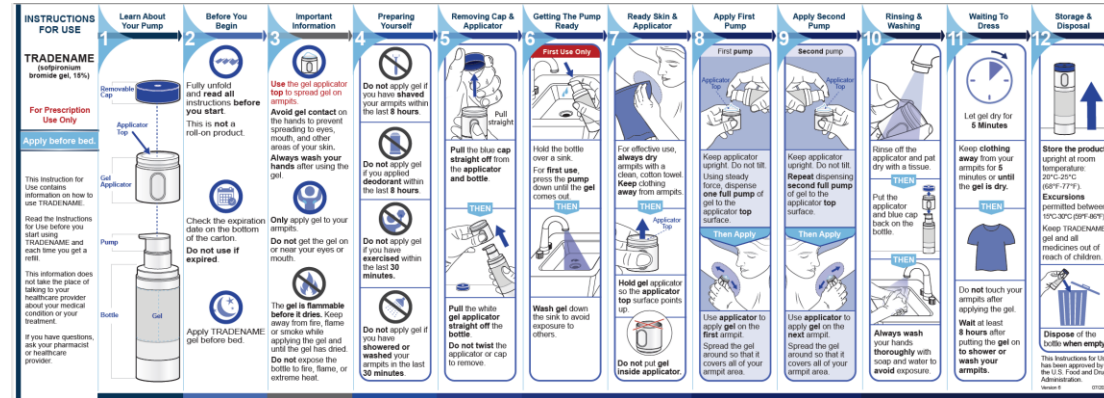
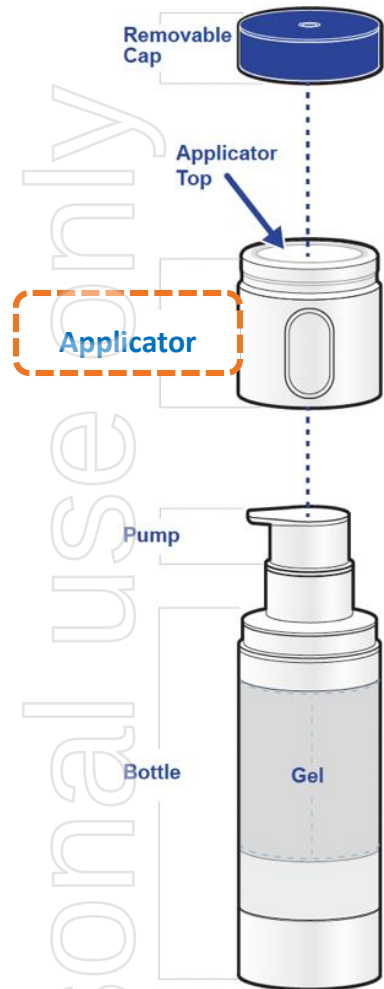
Instructions for Use – why are they needed?



Example – Axiron® Instructions For Use

- ❖ Sofpironium Bromide gel, 15% is a “combination product” in that it combines a drug (Sofpironium Bromide), with a dispenser pump and applicator, that is used to apply the drug
- ❖ Instructions For Use generally contain step-by-step written and visual instructions For Use, set out in a patient-friendly manner
- ❖ Instructions For Use generally go through multiple drafting iterations, informed by human factors validation studies, where volunteers read and follow the Instructions, to check whether they can correctly apply the drug in accordance with those Instructions
- ❖ FDA carefully reviews the Instructions for Use as part of its label review during the NDA review, to ensure that those Instructions support the safe and effective use of the drug (and avoids excess dosing, secondary exposures etc)

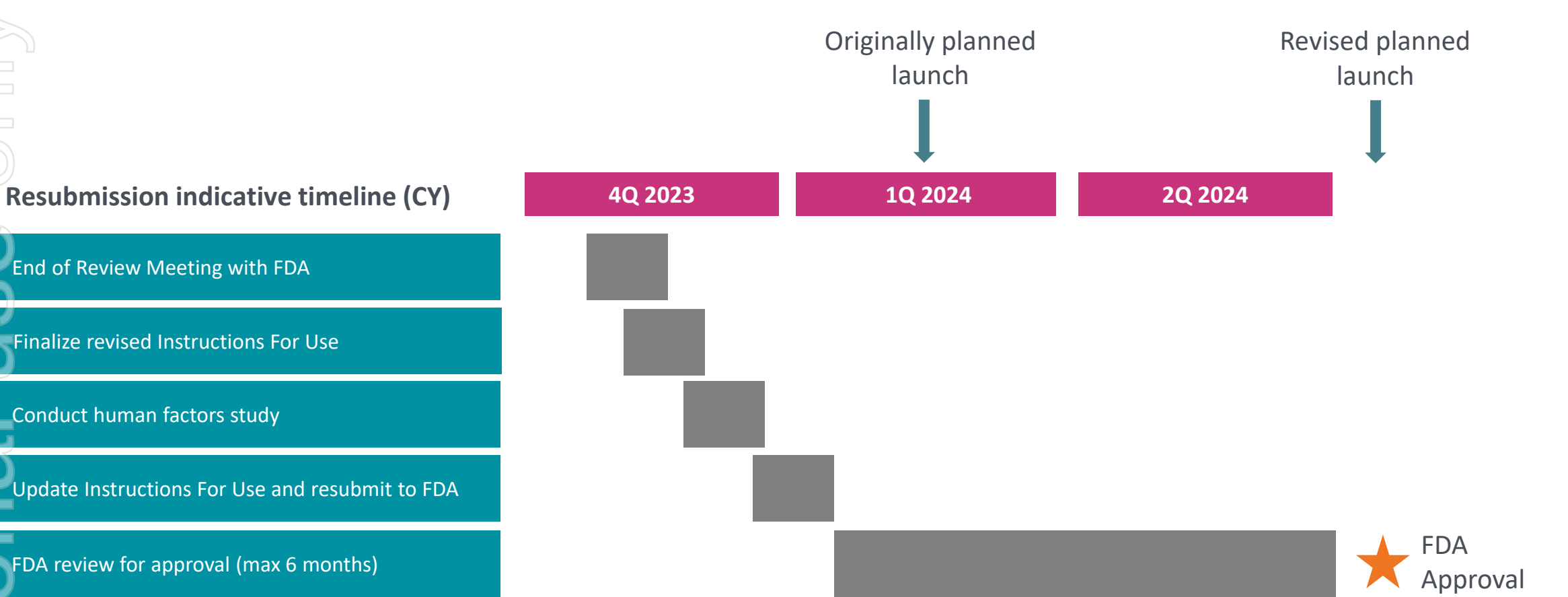
What does FDA want now?



1. Label gel applicator with “applicator”
2. Reformat the Instructions For Use so that it does not fold and “revise” the Instructions to further simplify the guidance for application
3. Place the statement “wash hands with soap and water immediately after use” on the outside of the carton and on the bottle prominently
4. Conduct another human factors validation study to demonstrate the revised Instructions For Use are capable of being followed to be able to apply Sofpironium Bromide gel safely and effectively

How long will this take - planned timeline

Rapid engagement with FDA, followed by short human factors validation study and resubmission - with a 6-month review clock



Impact on the commercial opportunity for Sofpironium Bromide?

Minimal delay in commercialisation and no impact on market opportunity

- ❖ Given commercialization was planned to commence in 1Q CY2024, the **delay caused by the resubmission is likely to be only 3-6 months**
- ❖ **No clinical efficacy, safety, pharmacology, non-clinical, or manufacturing issues were raised and no additional clinical studies are required by FDA - NDA approval pathway de-risked**
- ❖ **Large market targeting the ~3.7 million patients** currently in the doctor's office seeking therapies to treat their condition and the **~6.3 million patients seeking solutions** online
- ❖ Revised approval timetable allows for the **potential to also launch the digital and telemedicine platform following expected approval in mid-CY2024**
- ❖ **Botanix is funded to reach the new approval date** and will adjust operating costs and commercial spend to ensure runway extends appropriately

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Operations:

3602 Horizon Drive, Suite 160
King of Prussia PA 19406

Corporate Office:

Level 1, 50 Angove Street North
Perth W. Australia 6006

Authorised for release by Vince Ippolito, Executive Chairman

Botanix Pharmaceuticals Limited

