

Project Case Summary

Complete Response Letter Resolution and NDA Amendment

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Client:	<i>U.S. OTC pharmaceutical company</i>
FDA Reviewing Division:	<i>Division of Anti-Infective Drug Products and Division of Over-the-Counter Drug Products</i>
Project Profile:	<i>Topical antiseptic solution with applicator</i>

Beckloff Associates became involved in the project after client submitted their NDA.

1. Evaluated NDA information to determine potential deficiencies with development plan
2. Maintained IND, including preparation and submission of IND Amendments and Annual Reports
3. Provided consultation on CMC issues
4. Conducted cGMP audits and compliance program of drug product manufacturer
5. Interacted with the FDA on client's behalf, as needed
6. Provided consultation regarding FDA's "Complete Response" Letter resulting from two deficiencies in pivotal clinical study design prior to Beckloff Associates' project involvement
7. Addressed clinical study deficiencies
 - a. Developed pivotal clinical protocols
 - b. Identified 2 clinical sites and performed pre-study site visits
 - c. Implemented clinical studies
 - d. Monitored pivotal studies, including initiation, interim, and close-out visits
 - e. Arranged for GCP audits of sites by independent contractor
 - f. Evaluated clinical statistical reports
 - g. Prepared and submitted response to "Complete Response Letter"
 - h. Prepared and submitted NDA Amendments, including CMC, microbiology, and clinical data
 - i. Interacted with FDA during review of NDA Amendments
8. Assisted with preparation of product labeling
 - a. Prepared outline for client of label requirements for new drug based on FDA regulations, including outer carton (front, side, top, and back panels), inner carton (lidding), and specifications for drug facts box (box placement, font size and color, bullet size, hairline and box outline thickness, and text requirements)
 - b. Assisted with labeling layout.
 - c. Coordinated preparation of labeling with graphic artist
 - d. Reviewed and revised labeling
 - e. Printed draft labeling samples for FDA submission
 - f. Participated in labeling negotiations with FDA
 - g. Provided final labeling samples and marketing materials to FDA

9. Received NDA approval from FDA
10. Prepared supplement NDAs, including product and labeling supplements
11. Received approval from FDA on supplement NDAs involving 3 new products
12. Maintained NDA, including preparation and submission of NDA Amendments and Annual Reports, as needed

Outcome:	<i>All Complete Response Letter issues resolved to FDA satisfaction, NDA approved, supplement NDAs approved</i>
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