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To: This file

Date: November 21, 2022

STN: 125739/0

Submission Type: Original BLA

Applicant: Ferring Pharmaceuticals Inc.

Product: Fecal Microbiota, Live (REBYOTA™)

From: Margaret Dayhoff-Brannigan, PhD
Regulatory Review Branch 1 (RRB1)
Division of Vaccines and Related Products
Applications (DVRPA)
Office of Vaccines Research and Review (OVRR)

Through: Qun Wang, PhD
RRB1/DVRPA/OVRR

The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list.

Review Team:

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