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RESEARCH**

APPLICATION NUMBER:

22-353

ENVIRONMENTAL ASSESSMENT

**REQUEST FOR EXCLUSION FROM REQUIREMENT FOR ENVIRONMENTAL
ASSESSMENT**

Pursuant to 21 CFR 25.15(d) and 25.31(a), Mutual Pharmaceutical Company, Inc. (Mutual) hereby claims a categorical exclusion from the requirement of an Environmental Assessment.

Under 21 CFR 25.31(a), a categorical exclusion exists for:

Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

Mutual is requesting FDA to take action to approve this application for colchicine tablets USP, 0.6 mg for the treatment of acute attacks of gout. Mutual projects that the approval of its colchicine tablets will not increase the use of the active moiety because colchicine is currently marketed as a single ingredient without NDA approval. Eventual approval of this NDA will result in the replacement of the use of unapproved colchicine tablets of the same strength.

Mutual also certifies that, to the best of its knowledge and its opinion, it is in compliance with all federal, state, and local environmental protection requirements.

On the basis of the foregoing, Mutual claims that an Environmental Assessment is not required with this application and, therefore, requests that the application be categorically excluded from the requirement to submit and Environmental Assessment.