

LICENSING ACTION RECOMMENDATION

Applicant: _____ STN: _____

Product: _____

Indication / manufacturer's change :

- Approval:
- Summary Basis For Approval (SBA) included
- Memo of SBA equivalent reviews included
- Refusal to File: Memo included
- Denial of application / supplement: Memo included

RECOMMENDATION BASIS

- Review of Documents listed on Licensed Action Recommendation Report
Inspection of establishment
BiMo inspections completed
Review of protocols for lot no.(s)
Test Results for lot no.(s)
Review of Environmental Assessment
Review of labeling
FONSI included
Categorical Exclusion
None needed

CLEARANCE – PRODUCT RELEASE BRANCH

- CBER Lot release not required
Lot no.(s) in support – not for release
Lot no.(s) for release
Director, Product Release Branch

APPROVED
By Joseph Quander III at 1:55 pm, Feb 19, 2008

CLEARANCE – REVIEW

- Review Committee Chairperson:
Product Office's Responsible Division Director(s)*:
DMPQ Division Director* :

APPROVED
By Roman Drews at 6:57 pm, Feb 14, 2008

APPROVED
By Basil Golding at 5:38 pm, Feb 14, 2008

APPROVED
By John A. Eltermann, Jr. at 1:00 pm, Feb 20, 2008

* If Product Office or DMPQ Review is conducted

CLEARANCE – APPLICATION DIVISION

- Compliance status checked
- Acceptable
- Hold
- Cleared from Hold

Compliance status check Not Required
Regulatory Project Manager (RPM)

APPROVED
By Pauline Cottrell at 2:46 pm, Feb 14, 2008

Responsible Division Director
(where product is submitted, e.g., application division or DMPQ)

APPROVED
By Jeffrey Anderson at 11:43 am, Feb 20, 2008