

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 4:03 pm, Mar 18, 2008

CLEARANCE – REVIEW

Review Committee Chairperson: _____ Date: _____

APPROVED
By Laura Wood at 7:41 am, Mar 18, 2008

Product Office's Responsible Division Director(s)*: _____ Date: _____

APPROVED
By Basil Golding at 11:45 am, Mar 19, 2008

DMPQ Division Director* : _____ Date: _____

APPROVED
By John A. Eltermann, Jr. at 5:46 pm, Mar 18, 2008

* If Product Office or DMPQ Review is conducted

CLEARANCE – APPLICATION DIVISION

- Compliance status checked
- Acceptable
- Hold
- Cleared from Hold
Date: _____

Compliance status check Not Required
Regulatory Project Manager (RPM) _____ Date: _____

APPROVED
By Pratibha Rana at 12:22 pm, Mar 17, 2008

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

APPROVED
By Elizabeth Callaghan at 11:39 am, Mar 19, 2008