POLICY

OFFICE OF PHARMACEUTICAL QUALITY

Change in Hard Gelatin Capsule Shell Supplier

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PURPOSE

This MAPP establishes the policy in the Office of Pharmaceutical Quality (OPQ) for a postapproval change in the supplier of a hard gelatin capsule shell.

BACKGROUND

The intent of this MAPP is to clarify the reporting category for a change in supplier for a hard gelatin capsule shell.

POLICY

General Policy:

When an applicant changes the supplier of a hard gelatin capsule shell, with no change in capsule composition or appearance, the information should be submitted in an annual report. If a supplement is received containing a change in the supplier of a hard gelatin capsule shell, OPQ should inform the applicant that the described change is an annual reportable change.

Special Considerations:

Any change in capsule composition or appearance, including change in size, color or dye, or a change from gelatin to non-gelatin alternative, should be categorized as a prior approval supplement (PAS). [Ref. 1,2]

Reporting Requirements:

If any change in hard gelatin capsule shell supplier occurs, the applicant should be asked to provide the following information for review in the next annual report:

1. Full name and address of the new hard gelatin capsule shell supplier.
2. Certification from the new hard gelatin capsule shell supplier that the gelatin used conforms with USP/NF specifications for gelatin.
3. Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy (BSE/TSE) certification for gelatin from the new supplier.
4. Specification of the hard gelatin capsule shell from the new supplier, which should be consistent with existing specifications.

RESPONSIBILITIES

- The Office of Product Quality Assessment (OPQA) I and OPQA II assessment division (assessors and supervisors) will evaluate the submission and determine whether it is an annual reportable change. This should then be communicated to the Regulatory Business Project Manager (RBPM).
- The Office of Program and Regulatory Operations (OPRO) RBPM will inform the applicant that information on changes in hard gelatin capsule shell supplier is appropriate for submission in the annual report.

REFERENCES

1. FDA guidance for industry *Immediate Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation* (Nov 1995) and FDA guidance for industry *SUPAC IR Questions and Answers about SUPAC-IR Guidance* (Feb 1997).
2. FDA guidance for industry *Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules* (October 2022).
3. FDA guidance for industry *CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports* (Mar 2014).
4. United States Pharmacopoeia and the National Formulary (USP NF).

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
8/15/2016	Initial	N/A
2/21/2023	N/A	Recertified, no changes
N/A	N/A	12/23/2024 administrative changes made to reflect the 2024 OPQ reorganization.