

Determining When Pre-License / Pre-Approval Inspections are Necessary

SOPP 8410

Appendix 1

Waiver Memorandum

Date: [date]

From: [name], HFM-[], CMC Reviewer
[name], HFM-[], BLA Committee Chair

To: BLA File – STN [STN #]

Subject: Recommendation to waive a pre-license inspection

Sponsor: [Applicant], U.S. License # []

Contract: [contract manufacturer, if applicable]

Product: [name, including trade name]

Indication: [product's primary indication for use]

Through: [name, branch chief of CMC reviewer], HFM-[]
[name, branch chief/supervisor of committee chair], HFM-[]

Clearance Routing

[name] CONCUR DO NOT CONCUR DATE
Director, Division of Manufacturing and Product Quality, HFM-670
Office of Compliance and Biologics Quality, CBER

[name] CONCUR DO NOT CONCUR DATE
Director, Division of [product division], HFM-[]
[product office]

cc: [name, director of applications division], HFM-[]
[name], Branch Chief, Program Inspection Branch, HFM-604

Summary: [brief summary of memo]

Brief History

[Describe the nature of the submission, such as original application or supplement to describe manufacturing change.]

Facility Information

[Describe the operations performed at the site for which waiver of inspection is proposed.]

Supporting Information

[This section should include information to support the recommendation to waive the preapproval or pre-license inspection. The information should address the points in the SOPP, and should refer to previous inspection information, where applicable. The memo should include a statement that the criteria in the SOPP were evaluated. Where necessary, attachments may be included.]

Waiver Recommendation:

[brief summary of basis for recommendation and conclusion]

Signed:

[name, CMC reviewer], HFM-[] _____ DATE _____

[name, committee chair], HFM-[] _____ DATE _____