USP Revision Request Form

Please email the completed form to donations@usp.org. The donations team will review the request and create an entry within the USP Donor Portal (https://uspharm.force.com/dc/s/) for the secure sharing of support documentation.

Company Name:

Submitter Name:

Phone Number:

Email Address:

Details for Revision Request

https://www.usp.org/get-involved/donate/submission-guidelines

Monograph Name:

NDA/ANDA/DMF number

(For DMF holders, please indicate the (A)NDA the DMF is referenced in)

Application Status: [select]

For pending applications, please provide copies of any documentation from FDA recommending that you pursue the USP Pending Monograph process (you may redact sensitive information)

Comments regarding regulatory status:

GDUFA goal date (if applicable):

Requested test(s) for revision:

Please provide a **brief** explanation of the requested changes and include justification/ rationale for your request (monograph improvement/update, FDA request, out of compliance with current USP monograph, problem with the procedure, etc):

Links to Submission Checklists and Guidelines:

Submission Checklist

Accelerated Revision Process

Pending Monograph Guidelines

Supporting Information for Adding Dissolution Tests

Please note that the next step for your revision request is a series of reviews. If there are any additional data needs or questions, a USP staff member will reach out for the information required. Due to operational priorities, there may be a delay in addressing your request. In addition, after the request has been reviewed, the Documentary Standard Scientist and Expert Committee for this monograph will decide whether to pursue the revision request.