MEMORANDUM

TO: Joint Committee on Pharmaceutical Excipients

FROM: Brian Zamora, Chairperson

DATE: October 6, 2014

SUBJECT: Proposed revision to NSF/ANSI 363 – Good Manufacturing Practices for Pharmaceutical Excipients (363i1r7.2)

Draft 7 of NSF/ANSI 363 issue 1 is being forwarded to the Joint Committee for balloting. Please review the changes proposed to this standard and submit your ballot by October 20, 2014 via the NSF Online Workspace.

Purpose

The purpose of this ballot is revise section 8.2.4.5 to create better clarification.

Background

In a recent ballot of NSF 363 it was suggested that the document could be enhanced to create better clarification.

If you have any questions about the technical content of the ballot, you may contact me in care of:

Chairperson, Joint Committee
c/o Rachel M. Brooker
Joint Committee Secretariat
NSF International
Tel: (734) 827-6866
E-mail rbrooker@nsf.org
8 Measurement, analysis and improvement

8.2 Monitoring and measurement.

8.2.4 Monitoring and measurement of product

8.2.4.5 Certificates of analysis

The organization shall provide Certificates of Analysis to the required specification for each batch of excipient.

h) analytical results representative of the batch\(^1\), if not based on testing of a sample of the finished excipient, the basis of the results shall be communicated to the customer, (see NOTE below for alternatives to finished excipient testing, as appropriate);

*Reason: Better clarification. (Suggested by S. Wolfgang in the 9/11/14 ballot)*

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\(^1\) A supplier may provide results on the CoA from a method that has been demonstrated to be either equivalent or better than the specified method. See PQRI joint position paper on control strategies. [http://www.pqri.org/pdfs/Excipient_Position_Paper_Final_06212007.pdf](http://www.pqri.org/pdfs/Excipient_Position_Paper_Final_06212007.pdf)