TO: Joint Committee for Dietary Supplements

FROM: Brian Zamora, Chair of the Joint Committee

DATE: February 24, 2020

SUBJECT: Proposed revision to NSF/ANSI 173 – Dietary Supplements (173i62r1)

Revision 1 of NSF/ANSI 173, issue 62 – BioTract disintegration – Extended Release is being forwarded to the Joint Committee for consideration. Please review the proposal and submit your ballot by March 16, 2020 via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please use the comment template provided in the ballot and upload it online via the browse function.

Purpose

The proposed revision will update the timed-release section.

Background

USP general chapter <701> lists testing procedures for uncoated tablets, plain coated tablets, delayed release (enteric coated) tablets, buccal and sublingual tablets, as well as hard shell capsules and soft gelatin capsules. One of the required tests for products to achieve NSF certification is disintegration according to USP standards for the appropriate dosage form.

The patented BIO-tract® technology is designed to protect probiotic organisms from stomach acid and ensure delivery and controlled release to and through the intestinal tract. As such, standard USP disintegration tests, either for regular uncoated or enteric coated tablets/capsules, are not appropriate for use with tablets made using this technology.

Briefly stated, contact with stomach fluids creates a protective layer around the BIO-tract® tablet, which then moves into the intestinal tract where the contents are released from the core as it passes through the intestines. This delivers the live probiotics throughout the entire intestinal tract where they can be effectively used by the body. The delivery has been shown to proceed over 10-12 hours, delivering billions of live bacteria to the consumer. See accompanying PDF “Nutraceutix Dissolution Flyer” for more information.

Healthy Directions has partnered with Nutraceutix, the manufacturer using this patented technology, to manufacture several products for which it seeks NSF certification. In conjunction with this, we are proposing a modification to the requirements for disintegration that will allow for appropriately evaluating these products.
Public Health Impact

The new standard intends to have a positive impact on public health.

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

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Chair, Joint Committee for Dietary Supplements  
c/o Rachel Brooker  
Joint Committee Secretariat  
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4.3 Extended release

If the supplement is manufactured using an extended release technology not intended to follow the USP criteria, then intended release characteristics must be disclosed on the product label.

5. Product requirements

5.4.3 Timed or slow Extended release

Extended release Supplements such as those which claim “timed release” or “slow release” shall be tested for disintegration using the equipment described in the currently promulgated version of the USP. If the product is intended to conform to the USP then it must be tested as per the USP. If the product is not intended to conform to the USP, then the testing method shall employ simulated gastric fluid for one hour, followed by simulated intestinal fluid for up to an additional 11 hours. Testing shall be performed using 0.1 M hydrochloric acid as the immersion fluid for a time period no greater than 8 hours or for the time period indicated on the product label. The dosages shall not disintegrate within the first hour of immersion and the disintegration shall conform to any statements made in labeling regarding the product’s release characteristics; if the labeling claims no specific release timeframe, then the dosages shall disintegrate by the end of the test. In addition, the firm seeking certification shall submit to the certifying body appropriate, scientifically valid performance data and a scientifically valid narrative justification to explain why and how
the product is formulated for extended release and to verify that the product performs reproducibly from batch to batch; the certifying body shall have the sole discretion to determine whether the data and justification are adequate, except that any data and/or justification published in a peer-reviewed study shall be deemed adequate:

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