I Opening Remarks

Joint Committee (JC) Chairperson Brian Zamora. Zamora welcomed everyone and called the meeting to order. Rachel Brooker read the antitrust statement and completed roll call.

II Review of Agenda

Zamora asked for any additions to the agenda but none were voiced.

Motion: Darryl Sullivan motioned to accept the proposed agenda.
Seconded: Joe Betz
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

III Review of 2017 Meeting Summary

Zamora asked if there were any additions or corrections to the 2018 Joint Committee on Dietary Supplements meeting summary but none were voiced.

Motion: Sullivan motioned to approve the 2018 meeting.
Seconded: Betz
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

IV Membership Review

Brooker informed the group that JC with 8 Industry, 7 Users, and 6 Public Health (PH) members. This group is deficient in PH stakeholders, and R. Brooker requested that anyone who knows of a PH representative that would be interested in joining to please contact her after the meeting.

V Old Issues

A. DS-2016-3 BioTract disintegration 173i62

Discussion: Staci Eisner presented that the last time Betz had requested some data to show that the extended release was on purpose and for a good reason. Eisner stated that the main change to the issue paper was that she added language that a company would
have to provide such justification. Mike Harvey noted that there needed to be language about the data being scientifically valid. Brooker also added that “NSF” needed to be changed to “Certifying Body” as NSF cannot be specifically named. Fillinger was skeptical about stating that the CB gets to qualify the data. Eisner suggested adding language regarding “peer reviewed data”. Zamora commented that Eisner has some great feedback to edit the current issue paper for resubmission to either the TG or JC.

**Action item** – Eisner will edit the issue paper.

B. **DS-2016-8 Probiotic Viability 173i66**

**Discussion:** Bethany Watts presented the latest edition of the issue paper. The JC wanted the TG to discuss the new edits being presented. Betz had some editorial comments on the language. Zamora suggested that Betz send his comments to Watts.

**Action item** – Send back to the TG.

C. **DS-2016-9 Known Adulterants 173i67r4**

**Discussion:** Michael McGuffin reviewed the current known adulterants. He suggested deleting the substances that have not been seen in decades and to replace them with the three examples in 5.3.6 in the issue paper. Please see issue paper for details. Eisner reasoned that curcumin should be added to the list. McGuffin agreed and stated that the table should be revisited.

Betz suggested removing 5.3.5 siting that companies are supposed to be doing ID testing therefore telling people what they cannot have in their products is overkill. Eisner stated that she was not apposed to removing digitalis but added that the US does not have a great training program for botanicals for industry. She concluded that this standard needs to provide guidance and suggested calling out the AHPA list since it is more frequently and easily updated. Another attendee suggested calling out 21CFR117. Eisner responded that it was a great idea but it would not work in some places since not all companies follow both 21CFR111 and 21CFR117. Katie Fillinger pointed out that section 8 only references 21CFR111 and noted that this standard should not focus on US specific so that it could be used outside the US. Eisner suggested that it could be controlled through GMP or supply chain.

Zamora stated that since there is still quite a bit of discussion on this he is sending this issue paper back to the TG. Brooker noted that the TG that covers this issue paper is the Ingredient Review TG. She read the roster and pointed out that there is currently no chair. She asked if anyone would like to be the chair and Steven Dentali volunteered.

**Action item** – Send back to the TG.

D. **DS-2016-10 Botanical Identity**

**Discussion:** Brooker informed the group that Jake Larson, who is no longer with the JC, McGuffin, and Jane Wilson had a few calls to discuss the known adulterants and this issue paper but the conversations never made it to this issue paper. She will organize a new call with those listed plus the new chair, Dentali, as well as Trish Flaster and Wendy Applequist.

**Action item** – Brooker will set up a call.
E. DS-2018-1 Enzymes 173i75

**Discussion:** Alaina Perkins informed the JC that this issue paper was put on hold for the time being.

F. DS-2018-3 Formulation 173i77

**Discussion:** Fillinger informed the JC that this issue paper was put on hold for the time being.

**Action item** – Fillinger will take this conversation into consideration and resubmit the issue paper.

G. DS-2018-8 Ephedrine Alkaloids173i82

**Discussion:** McGuffin stated that Brooker had sent him some comments from the ballot. He summarized that one comment concerned about the new language was too US centric and not universal enough. McGuffin presented his suggested language bellow.

> Finished products that contain *Ephedra* spp. that are marketed in any country that regulates a maximum level of ephedrine alkaloids shall be confirmed to contain no more than the allowed amount of ephedrine alkaloids at a limit of detection of 0.1 ppm.

> Notwithstanding the prior paragraph, this requirement does apply to ingredients and finished products that consist of or are derived from *E. nevadensis* or *E. viridis* that are not manufactured to concentrate any naturally occurring ephedrine alkaloids. Examples of such exempt ingredients and products include tablets or capsules containing ground raw material from or simple tinctures of these species.

> Compliance with this Section shall be verified in accordance with Section 7.4.

**Motion:** Betz motioned to go to ballot with McGuffin’s new language.

**Seconded:** Paula Brown

**Objections:** None

**Abstentions:** None

**Vote by verbal affirmation:** None apposed.

Motion passed.

H. DS-2018-11 Section 7.1 SierraSil 173i85

**Discussion:** Michael Bentley first thanked the TG members for all their hard work over the last year on this issue paper and introduced Elliot Sigal who is a toxicologist for Intrinsik. Sigal gave a presentation on consideration of bioaccessibility and bioavailability for dietary supplements. For details on his presentation please see the meeting packet on the NOW.

One of the attendees asked how human variability will affect the bioaccessibility such as for immune compromised people. Sigal did not have that data. Brown noted that there was a lot of information on this for lead, but she could not find very much on arsenic. Sigal responded that there is a huge data base of toxicological information on arsenic exposure and risk. Sylvia Laman informed the task group and other NSF staff that there is no known precedent for using the BARGE method to derive an adjustment factor in any authoritative human health metal risk assessment. She cautioned that this would be an unconventional
approach for the JC to adopt. Bentley countered that there is not a request to change the tolerable limits, but just to look at the test procedures from a safety perspective with appropriate risk factors. He added that his company has done human studies that have shown not only very low bioaccessibility and ultimately bioavailability, but that lead is also pulled out of the body.

Eisner supported the idea that this kind of product should be in the standard and requested the in vivo human data. She suggested that it could be written in the standard that if you want to be certified you must submit this type of data. Fillinger remarked that the issue right now is that it is very prescriptive on who needs to evaluate the metals and if deviated from it should be clearly written into the standard with the expectation of what is an acceptable study. Brown supported adding some language to explain how to qualify that the data is scientifically valid.

Brown suggested the creation of a TG to discuss how to qualify the data and write that in the standard and volunteered to chair it. Eisner objected that a TG may not be the best use of everyone’s time and that there has to be something somewhere that could be used. Amanda Phelka noted that NSF does have the Health Advisory Board (HAB). The motion to form the TG passed and Brooker will connect Brown and Phelka.

Motion: Brown motioned to create a TG to discuss how to qualify the data.
Seconded: Betz
Objections: None
Abstentions: None
Vote by verbal affirmation: None apposed.
Motion passed.

Action item – Brooker to connect Brown and Phelka regarding the new TG.

VII New Issues

A. DS-2019-1 Section 5.4.3 Timed or slow release 173i87

Discussion: Zamora presented that this issue paper was turned in by NHK Laboratories but Brooker reached out to them multiple times and they have not responded. Zamora asked the JC if they would like to pursue this issue paper. A few JC members voiced that they did not want to pursue it and no one voiced the desire to work on it. With the lack of interest by the JC, Zamora withdrew the issue paper.

B. DS-2019-2 Hemp 173i88

Discussion: Rebecca Adams stated that the TG met several times and is still working on multiple issue papers. The issue paper she presented was the latest version. Please see the NOW for details. She added that there is an upcoming TG meeting October 29th to discuss the current comments from the last straw ballot.

Action item – Discuss in the upcoming TG meeting.

C. DS-2019-3 Residual Solvents 173i879

Discussion: Adams explained that this issue paper came out of the original hemp issue paper. It too was straw balloted and the TG is still working through the comments. The TG will hopefully complete the comments at the October 29th meeting as well.
**Action item** – Discuss in the upcoming TG meeting.

VIII **New Business & Next Meeting**

A. **New Business**

**Discussion:** Brooker informed the JC that NSF has filed a Project Initiation Notification (PIN) with ANSI for a hemp/cannabis standard. She noted that NSF has not moved forward with anything past the PIN but she wanted the JC to know that it was filed. She stated that while the JC will not be voting on it at this meeting, she wanted the group to think about if they would like to oversee this future standard.

Zamora asked if there was any other new business. None was voiced.

B. **2020 meeting**

**Discussion:** Brooker found that Supply Side 2020 will be October 26-30th and therefore she assumes that the floor will open on October 29th making the 2020 face to face meeting October 28th from 8:00 am to 12:00 pm PT.

IX **Adjournment**

**Motion:** Jost motioned to adjourn the meeting.

**Seconded:** Eisner

**Objections:** None

**Abstentions:** None

**Vote by verbal affirmation:** None apposed.

Motion Passed.
## Attendance

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<tr>
<th>Company</th>
<th>Name</th>
<th>Interest Category</th>
<th>Role</th>
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<tr>
<td>Missouri Botanical Garden</td>
<td>Applequist, Wendy</td>
<td>Public Health / Regulatory</td>
<td>Member</td>
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<td>Atkinson, Gisele</td>
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<td>Betz, Joseph</td>
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<td>Brooker, Rachel</td>
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