DDT COA #000013 **COMMENTS ON SUBMISSION**

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Regarding: DDT COA #000013 Briefing Package for the Functional Dyspepsia Symptom Diary (FDSD)

Dear Dr. Coons:

Please refer to your November 15, 2017 submission for qualification. We thank you for providing the documentation referred to above, including the Qualification Briefing Package of Development of the *Functional Dyspepsia Symptom Diary* (*FDSD*) Version 5.0: dated October 27, 2017. Additionally, we thank you for your continued work in this disease area in developing a patient-reported outcome (PRO) instrument. Your briefing package included your qualitative work and limited quantitative work in patients with functional dyspepsia (FD). After reviewing this submission, we believe it contains insufficient information to support a qualification review. A reviewable full qualification package should include at minimum:

- Cognitive debriefing report of the final version of the FDSD
- Cross-sectional measurement properties of the FDSD including test-retest reliability

A complete description of what should be included in the full qualification package can be found here:
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm593211.htm.

Additionally, as you go forward with continued development of the FDSD, please consider the following comments to assist you in your qualification efforts.

- We understand that this medical condition is challenging to diagnose. Currently, you proposed that FD can be subdivided into two diagnostic categories as defined by the ROME criteria:
    1. Postprandial distress syndrome (PDS) with main symptoms of postprandial fullness and early satiation

2. Epigastric pain syndrome (EPS) with main symptoms of epigastric pain and burning

Given that these conditions may coexist per the ROME diagnostic criteria, separating the target population into two distinct categories may be diagnostically challenging. You will need to clarify how you intend to handle the potential for overlap.

You will also need to describe how the total symptom score of the FDSD will be applied if only a PDS or EPS patient population is enrolled in a future clinical trial, and whether using one of the two populations will impact the ability to detect change of the FDSD or the magnitude of change that is clinically meaningful.

- CDER encourages requestors, including those in the qualification program, to consider the use of data standards as early as possible in the product development lifecycle so that they are incorporated into the design, conduct, and analysis of studies. Study data standards for submissions to CDER can be found at: www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm.

Please contact the COA Staff at COADDTQualification@fda.hhs.gov should you have any questions (refer to DDT COA #000013).

Sincerely,

Elektra J. Papadopoulos -S

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