Errata to the FDA Briefing Document

Nonprescription Drugs Advisory Committee Meeting

September 18, 2019

Division Memorandum

Page numbers refer to PDF page number. Added text appear in bold underline font. Deleted text appear in strikethrough font.

1. On page 16-17, replace Table 2 "Timeline of Key Regulatory Activities" with the table below.

Date	Key Presubmission Activity
6/18/2007	PIND meeting with McNeil Consumer Healthcare (original IND holder)
11/8/2007	IND 77479 submitted by McNeil, revised protocols for 2 PK studies and 1 pivotal efficacy trial (A6431111)
12/5/2007	All 3 studies placed on clinical hold, the 2 PK studies were allowed to proceed the following year.
9/22/2009	End-of-Phase 2 meeting: Trial A6431111 was initiated in Europe without Agency review of final protocol, the second efficacy study in naturalistic environment was proposed.
4/9/2010	SPA submitted for naturalistic trial
5/26/2010	SPA No Agreement letter sent by Agency
6/14/2010	Type A meeting package submitted to discuss SPA comments
2/16/2011	Final protocol submitted for naturalistic study A6431112
5/13/2011	A6431112 terminated
11/2/2011	Protocol NICTDP3038, new naturalistic trial sent as SPA
11/18/2011	SPA No Agreement letter sent by Agency
2/2/2012	Amended SPA submitted
3/15/2012	SPA No Agreement letter sent by Agency
4/27/2015	Amended Protocol NICTDP2028 submitted
6/29/2015	Sponsor changed to Johnson & Johnson Consumer Inc., McNeil Consumer Health Division
9/28/2016	Study report submitted for completed study CO-140121222102-SCCT (formerly NICTDP3038)
2/24/2017	Agency received Letter of Authorization granting GlaxoSmithKline Consumer Healthcare (GSKCH) permission to cross-reference IND 77479
3/21/2017	~~GSKCH met with Agency PIND 133467 regarding label comprehension and human factors studies.~~ **GSK had a Pre-NDA meeting with the Agency (Division of Nonprescription Drug Products) to obtain feedback on the content and format of the forthcoming drug application (NDA)**
3/2/2018	GSKCH requested another meeting to further discuss label comprehension and human factors studies
5/1/2018	Initial Pediatric Study Plan (iPSP) submitted by Sponsor, requested PREA waiver
5/24/2018	Agency provided written responses to Sponsor's questions in lieu of meeting

Date	Key Presubmission Activity
10/8/2018	~~PREA waiver granted by Agency~~ **GSK submitted Agreed Initial Pediatric Study Plan**
12/20/2018	NDA 208425 submitted~~. No pre-NDA meeting to discuss format and content was requested or held.~~

Source: Clinical Reviewer Synopsis of presubmission and submission activities
Abbreviations: GSKCH, GlaxoSmithKline Consumer Healthcare; IND, investigational new drug; iPSP, initial pediatric study plan; NDA, new drug application; PIND, preinvestigational new drug; PK, pharmacokinetic; PREA, Pediatric Research Equity Act; SPA, Special Protocol Assessment

2. On page 106, paragraph 8, 1st sentence should read: GSKCH met with the Agency March 21, 2017 to discuss ~~revised labeling, the pivotal label comprehension study and human factors~~ studies required for OTC approval of nicotine mouth spray.

3. On page 107, paragraph 2 should read: The Applicant submitted an initial pediatric study plan (iPSP) on May 1, 2018 to request a Pediatric Research Equity Act waiver, which was granted ~~October 8, 2018~~ **November 9, 2018**. Final NDA submission was December 20, 2018. ~~No pre-NDA meeting to discuss format and content was requested or held.~~