

# BakerHostetler

November 12, 2018

Mr. Duane Boise  
MMJ International Holdings  
1895 Preston White Drive  
Suite 101  
Reston, VA 20191

RE: Communications with FDA

Dear Mr. Boise:

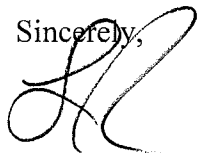
Per your request, please find a listing of filings made between MMJ International Holdings and the U.S. Food and Drug Administration.

Date	File name	Summary
November 28, 2017	MMJ Type B (Pre-IND) Meeting Request.pdf	First request for a Type B, pre-IND 137754 meeting
December 3/4, 2017	1.6.2 Pre-IND Meeting Briefing package.pdf	Amended request for a Type B, pre-IND 137754 meeting
December 7, 2017	Fwd pre-IND 137754 (CBDTHC soft gel) Information Request	Acknowledging the receipt of MS pre-IND 137754 meeting request and obtaining a PIND number.
December 11, 2017	<u>137754 2017 12 11</u> Acknowledge Pre-IND and Meeting Request Granted WRITTEN RESPONSES ONLY.pdf	Pre-IND 137754 meeting granted letter from FDA
January 3, 2018		Second request for a Type B, pre-IND 137754 meeting- additional background information
February 1, 2018	<u>137754 2018 02 01</u> Meeting Minutes WRITTEN RESPONSES ONLY.pdf	Written responses to the January 3, 2018 pre-IND 137754 package.

Date	File name	Summary
May 31, 2018	Cover Letter MMJ IND.pdf	IND 137754 package submitted to the FDA (cover letter) Multiple Sclerosis
June 22, 2018	Fwd IND 137754 (MMJ-001-T) Information Request	Request from the FDA review team related to their ongoing review of IND 137754.
June 28, 2018		Email response to the June 22, 2018 FDA request.
June 29, 2018	MMJ SN0002 Cover letter.pdf	Information Amendment: Chemistry, Manufacturing, and Controls (In response to the June 22, 2018 FDA request).
June 29, 2018	Amendment Form 1571.pdf	Investigational New Drug Application (IND) 137754 (Application form).
July 31, 2018		FDA Full Clinical Hold letter
August 1, 2018		Letter to FDA on face-to-face meeting on MMJ-002
August 7, 2018	Letter from FDA	Letter from FDA setting up PIND 140712 number and noting written responses only.
August 10, 2018		Letter to FDA withdrawing 140712 (so it can be amended).
August 14/15, 2018	Fwd IND 137754 (CBDTHC) Response	FDA response to August 14, 2018, email correspondence containing an inquiry regarding deficiency #4 of FDA July 31, 2018, Full Clinical Hold letter for IND 137754.
August 22, 2018	Letter from FDA	FDA letter re written responses only on pre-IND 140712
October 5, 2018	Pre-IND meeting Packet 140712 10-5-18.pdf	Pre-IND application 140712 Huntington's

\*FDA Orphan Designation Award 2/19

Sincerely,



Lee H. Rosebush  
Partner