



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 8, 2016

Obalon Therapeutics, Inc.
Amy VandenBerg
VP Clinical and RA
5421 Avenida Encinas
Suite F
Carlsbad, California 92008

Re: P160001
Trade/Device Name: Obalon Balloon System
Filed: January 7, 2016
Amended: January 19, 2016, June 13, 2016, and July 25, 2016
Product Code: LTI

Dear Amy VandenBerg:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Obalon Balloon System. The Obalon Balloon System (the "System") is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss in adults with obesity (BMI of 30 – 40 kg/m²) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 12 months for the Obalon Balloon Kit, Accessory Kit, and EzFill Can. Expiration dating for the EzFill Dispenser has been established and approved at 24 months. This is to advise you that the protocol you used to

establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, <http://www.fda.gov/udi>.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Two (2) copies of each report, identified as an "OSB Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

OSB Lead PMA Post-Approval Study – Obalon Balloon System Post-Approval Study: The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. On August 17, 2016 (by interactive e-mail review), you agreed to conduct a post-approval study as follows:

The Obalon Balloon System Post-Approval Study is a prospective, open-label, single-arm study of the safety and effectiveness of the Obalon 6-month Balloon System, as an adjunct to weight loss for obese adults 22 years of age and older with a Body Mass Index (BMI) of 30 kg/m² to 40 kg/m². This is a 12-month follow-up study in which subjects will be treated during the first 6 months with placement (via swallow) of up to three Obalon Balloons in conjunction with a moderate intensity weight loss and behavioral modification program standardized throughout the sites, followed by observational

evaluation for an additional 6 months after device removal. A total of 200 subjects will be enrolled at 10 to 15 sites in the United States; 180 evaluable subjects will be available at 6 months.

The primary endpoint is to evaluate the safety of Obalon by assessing the rate of device- or procedure-related Serious Adverse Event(s) (SAEs) (composite safety endpoint). Where the SAE is defined as any AE that results in death or persistent/significant disability and/or incapacity, which may include emergency room visits, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or requires medical/surgical intervention to prevent any of the above, through 6 months of treatment with the Obalon 6-month Balloon System. The observed rate will be compared to a performance goal of 10% at 6 months assuming an expected 4.5% device or procedure related SAEs rate. The secondary effectiveness endpoint is comprised (1) the mean % Total Body Loss (%TBL) and (2) the proportion of subjects achieving at least -5% TBL through the first 6 months after the device is implanted.

Additional endpoints include observational safety and effectiveness analyses including the percentage of subjects and frequency of individual Adverse Events (AEs) that are device- or procedure-related, frequency and cause of early explantations, rates of gastric ulceration, esophageal tear, balloon deflation, means of other weight loss metrics such as % Excess Weight Loss (EWL), Weight Loss (WL) in pounds, and BMI change, percentage of subjects with at least 6%, 7%, 8%, 9%, and 10% TBL, percentage of subjects with at least 25% EWL, patient-reported outcomes assessing tolerability of device and/or quality of life, weight loss metrics by number of balloons placed, weight loss metrics by frequency of weight loss and behavioral modification program counseling.

Follow-up assessments will be in office visits at Day 0, monthly during the first 6 months and at 12 months after initial implant. The Obalon 6-month Balloon System requires removal of all 3 balloons at the end of the 6-month period. Subjects will be followed for an additional 6 month period to ensure there are no Adverse Events as a result of balloon removal or residual events due to balloon use. Subjects with gastric ulcerations at the time of device explant will be followed with endoscopic evaluation every 8 weeks until the ulcer has visually resolved.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm>).

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described above. Your PMA supplement should be clearly labeled as an "OSB Lead PMA Post-Approval Study Protocol" as noted above and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm>.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at <http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
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If you have any questions concerning this approval order, please contact Joshua Silverstein at 301-796-5155 or Joshua.Silverstein@fda.hhs.gov.

Sincerely,

For Division

Douglas Silverstein -S
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Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
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