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

Amy Tezel, Ph.D.  
Associate Director, Regulatory Affairs  
Allergan, Inc.  
71S. Los Carneros Road  
GOLETA CA 93117-5506

Re: P000008/S017  
LAP-BAND™ Adjustable Gastric Banding System  
Filed: April 27, 2010  
Amended: August 12, September 24, and November 8, 2010  
Procode: LTI

Dear Dr. Tezel:

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) supplement for the LAP-BAND™ Adjustable Gastric Banding System.

The LAP-BAND® System is indicated for weight reduction for patients with obesity, with a Body Mass Index (BMI) of at least 40 kg/m<sup>2</sup> or a BMI of at least 30 kg/m<sup>2</sup> with one or more obesity related comorbid conditions.

It is indicated for use in adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device as modified 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 these restrictions on sale and distribution are 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.

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" (please use this title even if the specified interval is more frequent than one year) 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.

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 have also agreed to conduct two post approval studies that will evaluate the long-term effectiveness of the device and the incidence of adverse events. The first study will continue to follow patients enrolled in the investigational device exemption (IDE) pivotal study. The second study will enroll new patients from the Bariatric Outcomes Longitudinal Database (BOLD) registry database.

1. Study LBMI-002: this will be a multi-center, single arm, prospective, longitudinal study designed to gather data on the explant rate, adverse event rates, and successful weight loss. This study will continue to follow the 149 patients who were implanted during the investigational device exemption (IDE) pivotal study for five years post LAP-BAND® implantation. At five years, at least 112 patients will be included in the follow-up. The null hypotheses are: 1) the 5-year explant rate is not higher than 18% with a 14.5% superiority margin; 2) the 5-year successful weight loss (defined as 30 percent excess weight loss (EWL)) will be noted in at least 60% of patients; 3) data to be collected will include a yearly X-ray examination with barium swallow, hemoglobin A1c and lipid profile, in addition to all the data points in the pivotal study.
2. Study BOLD-001: this will be an observational, prospective, longitudinal study using the BOLD registry. The objective of this post-approval study is to evaluate the safety and effectiveness of the LAP-BAND® System in an obese population with a body mass index (BMI) of  $\geq 30\text{kg/m}^2$  and  $< 40\text{kg/m}^2$  and one or more obesity related comorbidities. Specifically, the study will assess long-term improvement in obesity-related comorbid conditions and percent excess weight loss. Other objectives are to evaluate safety (explant rate and other adverse events) by age, gender and race/ethnicity. The study duration will be 10 years. The null hypotheses are: 1) the explant incidence rate at five years is less than 6.5 per 100 person years; 2) the 5-year successful weight loss (defined as  $>30\%$  EWL) will be noted in at least 60% of patients; 3) the 10-year successful weight loss (defined as  $>30\%$  EWL) will be noted in at least 50% of patients; 4) there will be a significant decrease in the leading comorbidity factors of diabetes, hyperlipidemia and hypertension. A sample size of at least 845 patients will provide five year data and 90% power to detect a decrease of five (5) percentage points in the prevalence of diabetes (i.e., from a

baseline rate of 30% to a follow-up rate of 25%). A sample of 845 subjects would also provide sufficient information to analyze more than 80 variables that may predict or confound outcomes, or to identify potential subgroup differences.

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.

FDA would like to remind you that you are required to submit PAS Progress Reports every year. The PAS Progress Reports should be submitted separately from the Annual Reports. Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. 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 studies. Your PMA supplements should be clearly labeled as a "Post-Approval Study Protocol" 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 (i.e., since there are two post approval studies you must submit two separate PMA supplements). For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

([www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm) #2). You will submit reports on a 6-month schedule during the first two years and annually thereafter until the post-approval study is completed. The reports should clearly be identified as a Post-Approval Study Report.

Please be advised that the results from these studies 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.

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"

([www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm](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 [www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](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 [www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm](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 [www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMApprovals/default.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMApprovals/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 approved labeling in final printed form. Final printed 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 printed

labeling is identical to the labeling approved in draft form. If the final printed 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 triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information:

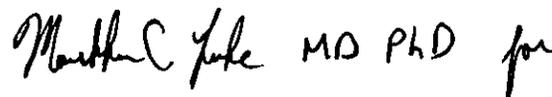
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>; clinical and statistical data:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm>)

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
PMA Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Ms. Kathleen M. Olvey at 301-796-6525.

Sincerely yours,



Christy Foreman  
Acting Office Director  
Office of Device Evaluation  
Center for Devices and Radiological Health