Standard Operating Procedure

Document Owner: Regulatory Affairs

Obalon Social Media Policy

REVISION HISTORY & DESCRIPTION OF CHANGES				
Rev	**CO No.**	**Description of Change**	**Author**	**Effective Date**
01	161212001	Initial release	K. Jaffe	12/21/16
02	170403001	Update for public Obalon page and closed patient group interaction	K. Jaffe	05/09/17

Section 1.0 Purpose

1.1 The purpose of this document is to describe the process for the use and monitoring of Social Media as it pertains to the Obalon Balloon System. It has been created to ensure all Obalon sales and marketing employees and/or anyone interfacing with Social Media to understand the Social Media policy concerning the Obalon Balloon System.

Section 2.0 Scope

2.1 This procedure applies to the monitoring of various social media for Adverse Event reporting

2.2 This procedure applies to the response to social media posts

2.3 This procedure applies to the posting of Obalon information on various social media

2.4 This procedure does not govern individual physician practice with regards to Social Media but does address the guidelines that are provided to practices

Section 3.0 References

3.1 WEB-0001 Obalon.com website

3.2 Obalon Facebook page

3.3 Obalon Facebook Patient Group

3.4 Obalon Twitter account

3.5 SOP-0068 Medical Device Reporting (MDR)

3.6 SOP-0044 Vigilance Procedure

3.7 SOP-0012 Retention of quality Records

3.8 SOP-0020 Customer Experience

3.9 FDA Guidances on Social Media:

- Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices , June, 2014
- Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, June, 2014
- Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, January, 2014
- Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, December, 2011

3.10 LIT-7500-0094: PR Toolkit

Section 4.0 Responsibilities

4.1 Marketing is responsible for managing the Obalon social media presence.

4.2 Quality Assurance is responsible for managing any potential product complaints or adverse events

4.3 Customer service is responsible for responding to the Customer Experience and communicating with other departments (e.g. Clinical, Regulatory) according to the policy laid out below.

4.4 All departments have responsibility to adhere to company policies regarding Social Media presence.

Section 5.0 Definitions

5.1. Sales and Marketing Employee: any internal employee hired by and working for the Sales and Marketing departments at Obalon

5.2 Social Media: any social internet presence – examples include: Facebook, Twitter, Instagram

5.3 Aware Date: an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

5.4 Adverse Event: any untoward medical occurrence in a patient or clinical investigation subject administered a medical product and which does not necessarily have a causal relationship with the treatment

5.5 Product Complaint: Customer Experiences that are any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device manufactured and/or distributed by the company.

5.6 Product Claim Advertising: Marketing pieces and statements that trigger the need for safety ("product claim ads")

5.7 Unbranded Advertising: marketing pieces and statements that do not require safety information ("unbranded ads"). Unbranded ads, would not require substantive legal review.

Section 6.0 Procedure

6.1 Social media creation
Marketing creates the collateral derived directly from already approved materials if claims are included.

6.2 Social media monitoring
Social media will be monitored bi-monthly (Twice per month) and as needed. The search records must be saved and stored for Quality System audits per SOP-0012. If there is an actual or potential product complaint, adverse event, or any illegal or inappropriate content, it must be forwarded directly to Customer Service immediately, within 24 hours per SOP-0020. Assessment and subsequent action should adhere to SOP-0068 and SOP-0044 for medical device reporting. All records of the responses on Social Media should be saved as a quality record.

6.2.1 Obalon Facebook Page: Any claim of safety or product performance on the Obalon managed Facebook Page should have a response from customer service. Sample responses are listed in the Appendix:

6.2.2 Obalon Closed Patient Group: On an ongoing basis as stipulated by this policy, customer service will review the patient posts that require feedback. These will be responded via private message.

6.3 Use of Safety Statement

6.3.1 On any Obalon-derived Social Media Page, include the following Safety Brief Statement (US ONLY): The Obalon Balloon System is intended for adults with a body mass index (BMI) of 30 to 40 kg/m^2 willing to follow a diet and exercise program. All Obalon balloons must be removed in 6 months. Patients with prior weight loss surgeries are not eligible. The most common side effects reported were mild abdominal pain and nausea which typically resolved within two weeks. You must take daily acid-blocking medicine prescribed by your doctor. For full Important Safety Information go to www.Obalon.com/safety-information or call your doctor.

6.3.2 For ALL Social Media Posts which include claims excluding Twitter include the following statement: For full Important Safety Information go to www.Obalon.com/safety-information or call your doctor.

6.3.3 For all Twitter Posts which include claims, include the following statement:
Visit obalon.com/risk

6.3.4 For all Twitter Posts safety information should be included on the main page so it is static

6.3.5 **For all Facebook Posts:**

6.3.5.1 Include safety information in the "About" section with link to safety page on obalon.com website

6.3.5.2 Should include AE reporting link and commenting/posting guidelines

6.3.5.3 Posts including any Obalon Balloon information should include safety information with a link to safety page on obalon.com website

6.3.5.4 Responses to posts about the Obalon Balloon should also include safety with a link to the safety page on obalon.com website

6.3.5.5 Videos posted must include safety in the segment or in surrounding text

6.4 Materials or content containing any patient information (i.e., protected health information) are prohibited without written consent from the patient.

6.5 Marketing and Regulatory Affairs are responsible for determining whether an ad contains a claim and requires legal review.

6.6 Product Advertisements:

6.6.1 Product claim advertisements must include safety information, even in character limited platforms such as Twitter.

6.6.1.1 Pieces that mention the Obalon Balloon System name and include any safety or efficacy claims. The inclusion of the indication is considered a claim.

6.6.1.2 Benefit information (*i.e.*, indications, usage and/or any other product claims) must be accompanied by risk information that is comparable in substance and look/prominence;

6.6.1.3 Product claim ads must include at a minimum the most serious risks (*i.e.*, those associated with a particular identifiable use or patient population)

6.6.1.4 Product claim ads must link (URL that contains word "risk") to more complete risk information (*i.e.*, not just company page, but dedicated risk page). A shortened URL is acceptable.

6.6.1.5 If accurate and balanced presentation of both risks and benefits is not possible within the constraints of the platform, then Obalon should not use the platform for the intended promotional messaging in accordance with FDA Guidance.

6.6.2 Unbranded Advertisements are low risk and do not need safety information. Examples of unbranded ads are:

i. General corporate information about the company (*e.g.*, Obalon is located in CA; Obalon is hiring)
ii. Disease awareness/education with no mention of the Obalon Balloon System (*e.g.*, obesity awareness; general exercise and diet information; health facts)
iii. Reminder ads (*e.g.*, mentions the Obalon Balloon System name only but not the indication or any suggestion/implication of the indication – "Check out the Obalon Balloon System!" or "The Obalon System is Now Available" (note, 6 month limit on "new" or "now available"))
iv. Weight loss treatment recommendations with no mention of Obalon Balloon (*e.g.*, "Interested in a weight loss treatment option?")

6.7 Personal Use of Social Media for Obalon is should be aligned with this procedure. All social media presence is governed through this SOP by the Marketing Department.

6.8 Use of Disclaimer Language

The Obalon Facebook presence should have appropriate disclaimer language.

Section 7.0 Appendices

1. Example Twitter communication

    a. Example – product claim ad
    o Obalon to facilitate weight loss in obese adults (BMI 30-40); not for prior weight loss surgery patients; risks include nausea obalon.com/risk
    o Failed to lose weight through diet/exercise? Try Obalon; not for those with prior weight loss surgery; risks include nausea obalon.com/risk
    b. Example – unbranded ad
    o Did you know that lachanophobia means fear of vegetables? Fear not! Eating your vegetables can help with weight loss!
    o According to the NIH, more than two-thirds of adults are considered to be obese – what can you do to combat the adult obesity epidemic?

2. Example Facebook communication (attached)
3. Example responses to social media posts:
    a. Hi Patient Name. We thank you for sharing your feedback and we'd like to follow up with you. Could you please send your contact information to socialmedia@obalon.com? Thanks!

    b. Hi Patient Name: We'd like to follow up with you to help troubleshoot the issues you are experiencing. Could you please send your contact information and patient's name to socialmedia@obalon.com? Thanks!

    c. Hi Patient Name. Thank you for reaching out! While the Obalon Balloon system is FDA-approved to allow users to begin their weight loss journey, the Obalon Balloon System requires a prescription from a healthcare provider (HCP) and we always encourage our users to work with their care team to determine an effective Weight Loss management plan. If you're interested, you can learn more here:<obalon patient portal>

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