# Allergan USA, Inc.
# LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg
# REPLACEMENT REQUEST FORM ("RRF")

Internal Tracking ID: _____

Allergan Use Only

## REPLACEMENT CONDITIONS

***This form is to be used for requests to:***

(1) replace a product that was accidentally dropped or contaminated pre-insertion*;
(2) replace a product that has come into contact with a patient but was not inserted successfully*;
(3) request a new unit for a patient following expulsion or removal for medical reasons*†;
(4) replace a unit due to a product quality complaint.

**Please provide the following information for ALL requests:**

**NOTE: Failure to complete this form in full may result in a delay in processing or a denial of the replacement request.**

Indicate Inserter Type: ☐ Single-Handed ☐ Two-Handed

Date of Request: _____

Contact Name: _____ Contact Title: _____

Contact Email Address: _____

Phone Number: _____ Fax Number: _____

Healthcare Facility Name: _____

Healthcare Facility Street Address: _____

Healthcare Facility City, State, ZIP: _____

Healthcare Facility LILETTA AccessConnect℠ Customer Account Number: _____

Healthcare Practitioner Name: _____

Healthcare Practitioner NPI #: _____ DEA #: _____

Return Unit Information: LILETTA Lot #: ☐☐☐☐☐-☐☐ Expiration Date: _____

Patient Initials: _____ Patient DOB: _____

** Replacement Request Form must be submitted within **thirty (30) days** of drop/contamination, incomplete insertion, or expulsion/removal.*

*† Note that a patient for whom a replacement request due to expulsion or removal for medical reasons is being submitted must sign her initials in acknowledgment of the replacement request on page 4 of this RRF.*

***CONTINUED ON NEXT PAGE***

**Please certify your request by checking ONE box corresponding to the reason for the replacement request:**

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**1. Accidentally Dropped or Contaminated Pre-insertion:**

☐ **Request to replace product that was accidentally dropped or contaminated pre-insertion within thirty (30) days of drop or contamination:**

- I certify that the unit I am seeking to replace has been accidentally dropped or inadvertently contaminated pre-insertion.
- I certify that the LILETTA unit being returned has not been contaminated with any human bodily fluids or tissue and in no way represents a biohazard.

Return Authorization # _____

*(For dropped or contaminated product pre-insertion cases, RA# to be provided by Allergan upon receipt of replacement request and required in advance of return.)*

**For accidentally dropped or contaminated pre-insertion cases, completed form must be emailed to Allergan LILETTA Customer Service Team at LilettaSupport@allergan.com within thirty (30) days after the drop or contamination. Upon acceptance of a signed complete form, a Return Authorization number ("RA"), pre-paid shipping label, and return instructions will be provided within two business days. Please return the product as instructed using the shipping label provided within thirty (30) days of receipt of return authorization. Any unit returned after thirty (30) days from receipt of the RA# and shipping instructions may, at Allergan's sole discretion, no longer be eligible for replacement. Any units returned for replacement without the RA# will not be processed for replacement. Allergan reserves the right to return or destroy units that are sent without prior return authorization. For questions, you may call our Customer Service team at 1.833.246.2386.**

***GO TO PAGE 4 TO COMPLETE THIS REQUEST***

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**2. Incomplete Insertion:**

☐ **Request to replace product that is contaminated due to an incomplete insertion procedure within thirty (30) days of incomplete insertion:**

Return Authorization # _____

*(For incomplete insertion cases, RA# to be provided by Allergan upon receipt of replacement request and required in advance of return.)*

**For incomplete insertion cases, completed form must be received by Allergan Quality Complaints via email at AUS-PSReporting@allergan.com or via fax at 800-972-2368 within thirty (30) days after the incomplete insertion. Upon acceptance of a signed complete form, a replacement LILETTA unit will be provided to the requesting Healthcare Practitioner whose associated Healthcare Facility and LILETTA AccessConnect℠ Customer Account Number appear on page 1 within approximately ten (10) business days.**

***GO TO PAGE 4 TO COMPLETE THIS REQUEST***

### 3. Expelled or Removed Units:

☐ **Request to replace product that is accidentally expelled or removed within thirty (30) days after expulsion or removal:**

- I certify that the LILETTA product reported on this form, for which the patient is requesting replacement, was expelled or removed for medical reasons by a trained medical professional from the patient whose initials and date of birth appear on page 1.
- I certify that I have reported the expulsion or removal for medical reasons to Allergan Quality Complaints at 1-855-LILETTA.
- I certify that LILETTA is a medically-appropriate product for the patient notwithstanding the expulsion or removal for medical reasons.
- I authorize the new unit to be shipped to my office, and I certify that such new unit will be reserved for the exclusive use of the patient whose initials and date of birth appear on page 1 and whose signed acknowledgment appears on page 4. If the patient does **not present I will return the unit to Allergan, per the instructions provided below.**

**For expelled or removed units, completed form must be received by Allergan Quality Complaints via email at AUS-PSReporting@allergan.com or via fax at 1.800.972.2368 within thirty (30) days after expulsion or removal for medical reasons by a trained medical professional. Upon acceptance of a signed complete form, a replacement LILETTA unit will be provided to the requesting Healthcare Practitioner whose associated Healthcare Facility and LILETTA AccessConnect℠ Customer Account Number appears above within approximately ten (10) business days. The unit will be provided for exclusive use of the patient whose Expelled/Removed Unit Information, Patient Initials, and Date of Birth appear on page 1 within approximately ten (10) business days. In the event the patient does not present to receive the replacement LILETTA unit or for additional questions, please call 1-855-LILETTA for information on how to return the unused unit to Allergan.**

*GO TO PAGE 4 TO COMPLETE THIS REQUEST*

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### 4. Product Quality Complaint:

☐ **Request to replace product due to suspected physical or mechanical defect in the product, its packaging, or labeling.**

**For product quality complaints, send completed form to Allergan Quality Complaints via email at AUS-PSReporting@allergan.com or via fax at 800-972-2368 to request a replacement. You will be contacted to provide information about the complaint. Your replacement request will be evaluated upon receipt by Allergan, and if Allergan determines, in its sole discretion, that a replacement is appropriate, a replacement unit will be issued.**

*GO TO PAGE 4 TO COMPLETE THIS REQUEST*

**Please provide a detailed description of and reason for the event leading to this request:**

_____

_____

_____

_____

**Date of Insertion:** _____ **Date of Event:** _____ **Was patient contact made with the unit?** ☐ YES ☐ NO

**Was the unit placed?** ☐ YES ☐ NO **Were the threads cut?** ☐ YES ☐ NO **If yes to both, would you describe the event as:** ☐ partial expulsion *or* ☐ complete expulsion *or* ☐ medical event requiring removal

**Is the unit available for return?** ☐ YES ☐ NO *(Note: Unit must be available for return to receive replacement.)*

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**Please complete your product replacement request by certifying the following:**

- I certify that the LILETTA product reported on this form, for which I am requesting replacement, was purchased by the Healthcare Practitioner Office/Customer Account identified herein.
- I certify that I am authorized to act for the Healthcare Practitioner Office/Customer Account for which I am signing.
- I certify that I will not bill the patient or the patient's insurer for the courtesy product replacement unit requested herein.
- I certify that no replacement will be requested for product that has not met the conditions set forth in the LILETTA Replacement Policy.
- I authorize the replacement unit to be shipped to my office for in-facility use.
- I certify that I have received the patient's written consent/authorization to release and disclose patient identifiable information contained in this form to Allergan, its subsidiaries, affiliates, and agents for the purposes set forth herein.

**I further certify that the information provided in this form is complete and accurate to the best of my knowledge and I agree to notify Allergan of any changes I become aware of which could affect the evaluation or consideration of this replacement request.**

**Signatures (Required):**

Healthcare Practitioner Signature (Required): _____

Print Healthcare Practitioner Name (Required): _____

**For Expelled or Removed Units ONLY, patient acknowledgment of this replacement request is required:**

Patient Acknowledgment – Initials Only (Required): _____

**ALL INFORMATION ON THIS FORM IS REQUIRED UNLESS OTHERWISE STATED, INCLUDING THE HEALTHCARE PRACTITIONER SIGNATURE. FAILURE TO COMPLETE THE FORM IN FULL MAY RESULT IN A DELAY IN PROCESSING OR A DENIAL OF THE REPLACEMENT REQUEST.**

**As instructed above, for units that have been dropped or contaminated pre-insertion, please send completed form to the Allergan LILETTA Customer Service Team via email at LilettaSupport@allergan.com. For all other units, please send completed form to Allergan Quality via email at AUS-PSReporting@Allergan.com or via fax at 1.800.972.2368. If you have questions or require additional information, please contact the Allergan Customer Service Team at 1-855-LILETTA (1-855-545-3882).**