

# Patient Enrollment Form

## The FOCUS™ Program for ONSOLIS™



### Patient Authorization for Disclosure and Use of Health Information Statement

#### The FOCUS™ Program for ONSOLIS™

By my signature on the ONSOLIS™ Patient Enrollment Form, I hereby authorize each of my physicians, pharmacists, and other healthcare providers (my "Providers") and each of my health insurers (my "Insurers") to disclose my personally identifiable health information, including my medical diagnosis, condition, and treatment (including prescription information), my health insurance, and my name, address, and telephone number (my "Health Information") to BioDelivery Sciences International, Inc. (BDSI; sponsor)/MEDA Pharmaceuticals Inc. (Meda; licensee), their agents and representatives, including third parties authorized by BDSI/Meda to administer the FOCUS™ Program for the following purposes:

1. Enroll me in the FOCUS™ Program, administer my participation in the program (including contacting me), evaluate the safety of ONSOLIS™ and the effectiveness of the program, provide me with educational information on the FOCUS™ Program and my medical condition, and enroll me in appropriate assistance programs;
2. Contact my Providers regarding shipment and receipt of ONSOLIS™;
3. Contact my Providers to collect, enter, and maintain my Health Information in a database;
4. Submit information to government agencies and other authorities, such as the FDA, regarding such matters as adverse events and the FOCUS™ Program;
5. Contact my Insurers as needed to verify my insurance coverage, review reimbursement issues, and assist with adjudication of claims;
6. Further use and disclosure of my Health Information as required or permitted by applicable law; and
7. Use or disclosure of my de-identified Health Information (all personal identifiable information has been removed) as permitted by applicable law.

I understand that federal privacy laws may no longer protect my Health Information after its disclosure to BDSI/Meda and that it may be subject to re-disclosure. However, BDSI/Meda agree to protect my Health Information by using and disclosing it only for the purposes described.

I understand that I am not required to sign this Authorization. If I do not sign, I may not enroll in the FOCUS™ Program to receive ONSOLIS™ and may not receive the other services described above. Otherwise, my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits will not be directly affected if I do not sign this Authorization.

I understand that I may revoke (withdraw) this Authorization at any time by sending a signed, written request to the FOCUS™ Program by:

- fax to 1-800-558-6302, or
- mail to PO Box 52024  
Phoenix, AZ 85072.

BDSI/Meda shall notify my Providers and Insurers of my revocation, who may no longer disclose my Health Information to BDSI/Meda once they have received and processed that notice. However, revoking this Authorization will not affect BDSI's/Meda's ability to use and disclose my Health Information that it has already received to the extent permitted under applicable law. If I revoke this Authorization, I may no longer participate in the FOCUS™ Program to receive ONSOLIS™ and the other services described above.

This Authorization expires ten (10) years from the date that I enroll in the FOCUS™ Program.

I understand and agree with the terms and conditions of this Authorization. I also understand that I will receive a copy of this Authorization.

For more information about ONSOLIS™, please see Full Prescribing Information, including BOXED WARNINGS.



**Wholesaler/Distributor Enrollment Form**  
**The FOCUS™ Program for ONSOLIS™**



**I understand that ONSOLIS™ is available only through the FOCUS™ Program, I agree to comply with the program requirements, and acknowledge that:**

1. I will ensure that relevant staff are trained about the FOCUS™ Program for ONSOLIS™ procedures.
2. I will ensure that relevant staff distribute ONSOLIS™ only to FOCUS™ pharmacies that are active in the database.
3. I will provide monthly records of ONSOLIS™ shipments for each FOCUS™ pharmacy to the FOCUS™ Program.
4. I will permit a program-related audit of our shipping records to corroborate that we are shipping ONSOLIS™ only to FOCUS™ pharmacies.

\_\_\_\_\_  
Wholesaler's/Distributor's Authorized Representative Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Title

**Wholesaler Information**

Wholesaler/Distributor Name \_\_\_\_\_  
DEA Registration Number \_\_\_\_\_  
Primary Ship to Address \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_  
Office Phone \_\_\_\_\_ Office Fax \_\_\_\_\_  
Wholesaler/Distributor Point of Contact \_\_\_\_\_ Phone \_\_\_\_\_  
Fax \_\_\_\_\_ E-mail \_\_\_\_\_

Please fax this completed form to the FOCUS™ Program for ONSOLIS™ at 1-800-558-6302.

For questions regarding the FOCUS™ Program for ONSOLIS™, call 1-877-466-7654 (1-877-4ONSOLIS).

For more information about ONSOLIS™, please see Full Prescribing Information, including BOXED WARNINGS.



-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Bob Rappaport  
7/16/2009 11:02:24 AM