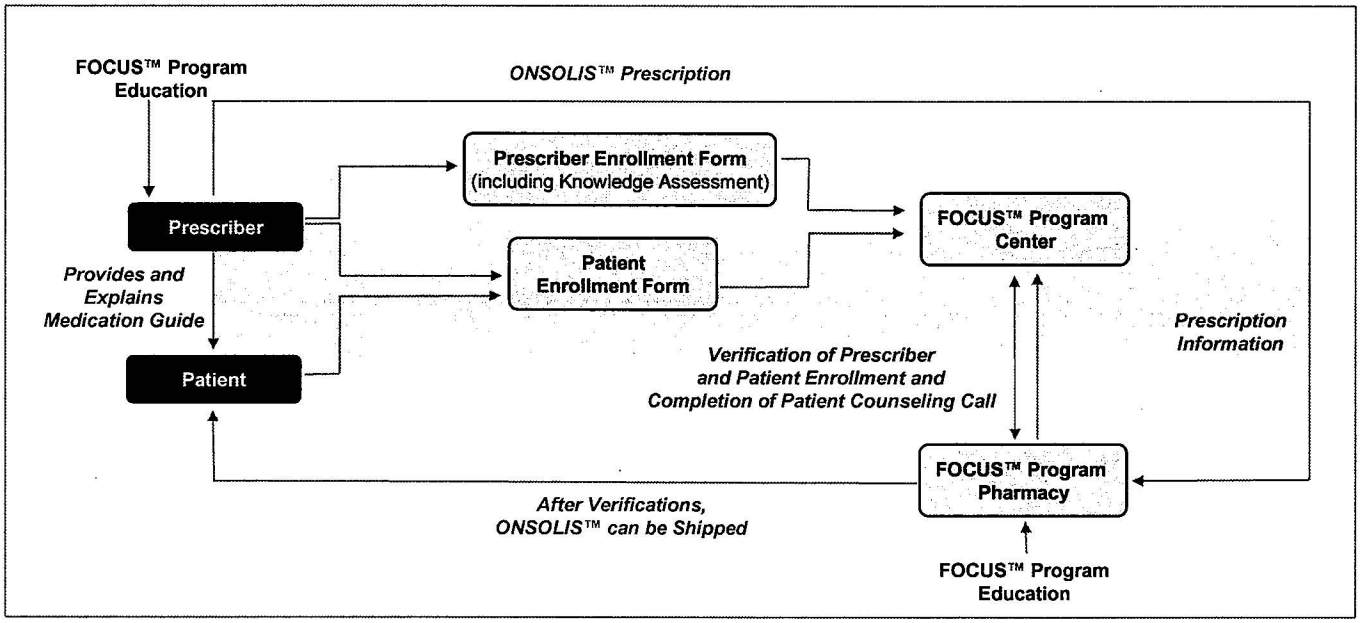
Overview of the FOCUS™ Program for ONSOLIS™



The FOCUS™ Program for ONSOLIS™ is designed to provide facilitated, managed distribution with training and enrollment of all stakeholders involved. The purpose of this program is to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors. Every prescriber, patient, wholesaler/distributor, and FOCUS™ Program pharmacy is required to enroll in the program. As a result, any stakeholder involved in prescribing, dispensing, or receiving ONSOLIS™ will have been trained on its safe use conditions. This program may also minimize the risk of drug diversion and fraudulent prescriptions.

The key elements of program are:

- Enrollment of all healthcare providers who will be prescribing ONSOLIS™;
- Enrollment of all patients prior to being prescribed ONSOLIS™; and
- Creation of a dispensing process that utilizes only enrolled pharmacies to help assure safe dispensing of ONSOLIS™.

Overview of the FOCUS™ Program for ONSOLIS™ (cont'd)

Prescriber Enrollment

The prescriber education and enrollment process is comprised of the following 3 steps that must be completed prior to prescribing ONSOLIS™:

1. The prescriber reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The prescriber completes and signs the Prescriber Enrollment Form (including Prescriber Knowledge Assessment) and faxes it to the FOCUS™ Program.
3. A FOCUS Program professional reviews the form, requests any missing or illegible information, and, when the necessary forms have been verified to be accurate and complete (including successful completion of the Prescriber Knowledge Assessment), the prescriber is notified of activation.

Prescribers will be re-educated (complete review of all educational materials) and re-enrolled (including Prescriber Knowledge Assessment) following substantial changes to the program or at least every 2 years.

Patient Enrollment

The patient (or legally authorized representative) counseling and enrollment process is comprised of the following 5 steps that must be completed prior to dispensing the patient's first prescription of ONSOLIS™:

1. The prescriber counsels the patient on the Medication Guide for ONSOLIS™
2. The prescriber and patient complete and sign the Patient Enrollment Form and the prescriber faxes it to the FOCUS™ Program.
3. A FOCUS Program professional reviews the form and requests any missing or illegible information.
4. The FOCUS Program counseling call to the patient is completed.
5. When the previous steps have been successfully completed, the prescriber and pharmacy are notified of patient activation.

Patients will be re-counseled (complete review of the current Medication Guide for ONSOLIS™) and re-enrolled following substantial changes to the program or at least every 2 years. If an active patient transfers to another active prescriber, the patient and new prescriber must complete a new Patient Enrollment Form.

Pharmacy Enrollment

The FOCUS™ pharmacy education and enrollment process is comprised of the following 3 steps that must be completed prior to receiving ONSOLIS™ inventory for dispensing:

1. The Pharmacist-in-Charge reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The Pharmacist-in-Charge completes and signs the Pharmacy Enrollment Form and faxes it to the FOCUS™ Program.
3. A FOCUS Program professional reviews the form, requests any missing or illegible information, and, when the form has been verified to be accurate and successfully completed, the pharmacy is notified of activation.

FOCUS™ pharmacies will be re-educated (complete review of all educational materials) and re-enrolled following substantial changes to the program or at least every 2 years.

Overview of the FOCUS™ Program for ONSOLIS™ (cont'd)

Prescription Processes

Process for Initial Prescription

The first prescription for ONSOLIS™ is processed by the FOCUS pharmacy according to the following 2 steps:

1. Prescriber faxes the initial prescription for ONSOLIS™ to the FOCUS™ Program to start the verification process. Prescriber sends the original, hardcopy prescription via a secure, traceable courier to an active FOCUS pharmacy. The original, hardcopy prescription must be received by the FOCUS pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
   a. Prescriber is active in the FOCUS™ Program,
   b. Patient is active in the FOCUS™ Program through the current prescriber, and
   c. Patient has successfully completed a FOCUS™ Program counseling call to review the safe use conditions and to ensure that their prescriber has performed the following steps prior to dispensing ONSOLIS™:
      i. counseled the patient (or legally authorized representative) that they must be regularly using another opioid pain medicine for their constant pain and their body must be used to this medicine (opioid tolerant),
      ii. counseled the patient (or legally authorized representative) on appropriate product use and contraindications, and
      iii. provided a Medication Guide for ONSOLIS™ to the patient (or legally authorized representative) and reviewed it with them.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

Process for Subsequent Prescriptions

Subsequent prescriptions for ONSOLIS™ by the same prescriber for the same patient are processed according to the following 2 steps:

1. Prescriber sends the original, hardcopy prescription for ONSOLIS™ via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
   a. Prescriber is active in the FOCUS™ Program,
   b. Patient is active in the FOCUS™ Program through the current prescriber, and
   c. Patient has previously received a prescription for ONSOLIS™ and successfully completed a FOCUS™ Program counseling call.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

Pharmacy Enrollment Form

The FOCUS™ Program for ONSOLIS™

Onsolis® fentanyl buccal soluble film ©

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 and document that all pharmacy staff who will process or dispense prescriptions for ONSOLIS™ are trained about the FOCUS™ Program for ONSOLIS™ procedures and educational materials. This training documentation is subject to audit.
2. I will ensure that pharmacy staff dispense ONSOLIS™ only after confirming (via FOCUS™ Program database authorization) that patients have met the following safe use conditions:
   a. Patients have been enrolled in the program, based on a valid prescription from an active prescriber;
   b. Patients or legally authorized representatives have been counseled regarding the importance of being on an around-the-clock opioid regimen for an adequate amount of time to ensure that they are opioid tolerant. Patients considered opioid tolerant are those who are regularly taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer; and
   c. Patients or legally authorized representatives have been counseled on appropriate ONSOLIS™ product use.
3. I will ensure that pharmacy staff provide a Medication Guide for ONSOLIS™ to every patient each time a prescription is dispensed.
4. I will ensure that pharmacy staff will not substitute ONSOLIS™ for any other oral transmucosal fentanyl citrate product.
5. I will provide reports of ONSOLIS™ prescription activity to the FOCUS™ Program for ONSOLIS™.
6. I will permit a program-related audit of my pharmacy to establish that ONSOLIS™ is dispensed only after documenting the above safe use conditions.

_____ _____

Pharmacist-in-Charge Signature Date

_____ _____

Print Name Title

Pharmacy Information

Pharmacy Name _____

Pharmacist Name _____ DEA Registration Number _____

Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Office Fax _____

Pharmacy 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.

MEDA PHARMACEUTICALS®

Onsolis™
fentanyl buccal soluble film ©

Important Prescribing Information About ONSOLIS™ (fentanyl buccal soluble film).

Dear Pharmacist:

MEDA Pharmaceuticals Inc. is introducing ONSOLIS™, a new treatment indicated only for breakthrough pain in patients with cancer, 18 years of age and older. ONSOLIS™ can only be used in patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.

ONSOLIS™ contains fentanyl, an opioid agonist and a Schedule II controlled substance, with abuse liability similar to other opioid analgesics. This should be considered when prescribing or dispensing ONSOLIS™ in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances, which include morphine, oxycodone, hydromorphone, oxymorphone, and methadone, have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

Serious adverse events, including deaths, in patients treated with other oral transmucosal fentanyl products have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of ONSOLIS™ for any other fentanyl product may result in fatal overdose.

ONSOLIS™ is contraindicated for use in opioid non-tolerant patients including those using opioids intermittently, on an as needed basis.

ONSOLIS™ is contraindicated in the management of acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients treated with other fentanyl products.

When dispensing, do not substitute an ONSOLIS™ prescription for any other fentanyl product. Substantial differences exist in the pharmacokinetic profile of ONSOLIS™ compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of ONSOLIS™ for any other fentanyl product may result in fatal overdose.

Special care must be used when dosing ONSOLIS™. If the breakthrough pain episode is not relieved, patients should wait at least 2 hours before taking another dose.

ONSOLIS™ is intended to be used only in the care of opioid tolerant patients with cancer and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

Patients and their caregivers must be instructed that ONSOLIS™ contains a medicine in an amount which can be fatal in children, in individuals for whom it is not prescribed, and in those who are not opioid tolerant. All ONSOLIS™ films must be kept out of the reach of children.

The concomitant use of ONSOLIS™ with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

Because of the risk for misuse, abuse, and overdose, ONSOLIS™ is available only through a restricted distribution program, called the FOCUS™ Program. Under the FOCUS™ Program, only prescribers, pharmacies, and patients registered with the program are able to prescribe, dispense, and receive ONSOLIS™. To enroll in the FOCUS™ Program, call 1-877-466-7654 (1-877-4ONSOLIS) or visit www.OnsolisFocus.com.

The FOCUS™ Program has been implemented to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors by: helping to assure proper patient selection, including avoidance of the use of ONSOLIS™ in opioid non-tolerant patients; reducing the risk of exposure to ONSOLIS™ in persons for whom it was not prescribed, including accidental exposure in children; and training prescribers, pharmacists, and patients about proper dosing and administration. Enrolled patients receive ONSOLIS™ directly from a specialty pharmacy, which delivers the medication via a secure, traceable courier.

Adverse Reactions

The adverse reactions seen with ONSOLIS™ are typical opioid side effects in a population with cancer. Frequently, opioid-associated adverse reactions will cease or decrease in intensity with continued use of ONSOLIS™. **Expect opioid side effects and manage them accordingly.** The most serious adverse reactions associated with all opioids including ONSOLIS™ are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. Follow all patients for symptoms of respiratory depression.

The most common adverse reactions are: nausea, vomiting, dizziness, anemia, dehydration, peripheral edema, dyspnea, and somnolence.

We appreciate your time and consideration and look forward to offering you and your patients continued support.

Sincerely,

[signature]

[name, title, MEDA Pharmaceuticals Inc.]

(Films shown actual size)

Please see accompanying Full Prescribing Information, including BOXED WARNINGS.

MEDA PHARMACEUTICALS®

Patient Program Overview

The FOCUS™ Program for ONSOLIS™

Onsolis
fentanyl buccal soluble film ©

The FOCUS™ Program for ONSOLIS™

The program requires the education of prescribers, pharmacists, patients, and caregivers regarding the safe use of ONSOLIS™.

Your doctor has determined that ONSOLIS™ may help control your pain. Before you can receive ONSOLIS™, you or your legally authorized representative must enroll in the FOCUS™ Program and agree to all program requirements.

The FOCUS™ Program includes the following:

- Your healthcare provider will review the Medication Guide for ONSOLIS™ with you and provide you a copy
- Together, you and your healthcare provider will **complete the Patient Enrollment Form**
- Your healthcare provider will send your enrollment form and prescription for ONSOLIS™ to the FOCUS™ Program
- A FOCUS™ Program professional will contact you (or your legally authorized representative, if applicable) by telephone to provide additional counseling.

  (This call must be completed before you can receive ONSOLIS™ for the first time.) Please provide us with a telephone number where you (or your legally authorized representative, if applicable) can be reached and tell us the best time to reach you.
- The FOCUS™ pharmacy will confirm your shipping address and schedule a delivery time.

For questions, visit www.OnsolisFocus.com or contact us directly at **1-877-466-7654 (1-877-4ONSOLIS)**

MEDA PHARMACEUTICALS

Patient Enrollment Form

The FOCUS™ Program for ONSOLIS™

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As the *prescriber* of ONSOLIS™, I acknowledge that:

1. This patient being prescribed ONSOLIS™ is opioid tolerant: patients considered opioid tolerant are those who are regularly taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for one week or longer.
2. This patient has been using around-the-clock opioid analgesia for at least 1 week.
3. This patient or a legally authorized representative has been counseled about the risks and benefits and appropriate use of ONSOLIS™, and about the risks of overdose due to giving ONSOLIS™ to someone for whom it has not been prescribed as described in the Medication Guide for ONSOLIS™.
4. I have provided and reviewed the Medication Guide for ONSOLIS™ with this patient or a legally authorized representative.

Prescriber Signature _____ Date _____

Prescriber Name, Credentials _____

DEA Registration Number _____ Prescriber Fax Number _____

As the *patient* being prescribed ONSOLIS™ or a legally authorized representative, I acknowledge that:

1. My prescriber gave me a copy of the Medication Guide for ONSOLIS™ and reviewed it with me. I have asked my prescriber all the questions I have about ONSOLIS™. I will ask my prescriber if I have any additional questions in the future about the use of ONSOLIS™.
2. I understand that there can be serious risks, especially if I do not take ONSOLIS™ as directed.
3. I understand that I must be regularly using another opioid ("narcotic") pain medicine for my constant pain. This is important because my body must become used to opioid medicine before I can take ONSOLIS™ (I am "opioid tolerant").
4. I agree that I will never give ONSOLIS™ to anyone else, even if they have the same symptoms, since it may harm them or even cause death.
5. I will store ONSOLIS™ in a safe place away from children because accidental use by a child is a medical emergency and can result in death.
6. I have reviewed the Patient Authorization for Disclosure and Use of Health Information Statement and I agree to its terms and conditions to authorize my healthcare providers and health plans to disclose my personal and medical information to BioDelivery Sciences International, Inc. (sponsor) / MEDA Pharmaceuticals Inc. (licensee) and their agents and contractors.

Patient Signature/Date _____

Personal Representative Signature/Date _____

☐ Spouse ☐ Legal Guardian
☐ Designated Representative per Power of Attorney

Personal Representative Name (Printed) _____

Patient Name (Last) _____ (First) _____ ☐☐ / ☐☐ Birthday (Month and day) _____ Zip code (5 digits)

Telephone number where you or your legally authorized representative can be reached _____

Time of day to call: Morning ☐ Afternoon ☐ Evening ☐

Fax a completed, signed copy of this enrollment form to the FOCUS™ Program for ONSOLIS™ at 1-800-558-6302.

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

MEDA PHARMACEUTICALS®