

## AVEED™ REMS Healthcare Setting Enrollment Form

### Instructions

AVEED is only available through the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program. In order to dispense and administer AVEED, each healthcare setting must:

1. Designate an Authorized Representative.
2. Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information.
3. Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years.
4. Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements.

For online enrollment, please go to [www.AveedREMS.com](http://www.AveedREMS.com).

For enrollment via fax, please complete all required fields on the next page and fax the page to **1-855-755-0495**. You will receive enrollment confirmation via your preferred method of communication (email or fax) within two business days.

For questions regarding the AVEED REMS Program, please either visit [www.AveedREMS.com](http://www.AveedREMS.com) or call the AVEED REMS Program at **1-855-755-0494**.

### Authorized Representative Responsibilities

I am the Authorized Representative designated by my healthcare setting to coordinate the activities of the AVEED REMS Program. I agree to comply with the following program requirements:

- I understand that my healthcare setting must be certified with the AVEED REMS Program to order or administer AVEED.
- I have completed the AVEED REMS Education Program for Healthcare Settings.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED.
- I understand this healthcare setting must renew its enrollment in the AVEED REMS Program every two years from the date of initial enrollment.
- This healthcare setting has the necessary on-site equipment and personnel to manage POME or anaphylaxis.
- This healthcare setting will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe use conditions required in the AVEED REMS Program, including the following:
  - All Healthcare Providers (HCPs) who prescribe AVEED in my healthcare setting are specially certified.
  - All non-prescribing HCPs who administer AVEED in my healthcare setting are trained and a record regarding such training must be maintained.
  - Prior to initiating treatment and before each injection, review with and provide a copy of “What You Need To Know About AVEED Treatment: A Patient Guide” to each patient to inform them about the risks of serious POME reactions and anaphylaxis.
  - To observe each patient administered AVEED for **30 minutes** at my healthcare setting following each injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- Not to loan, sell or transfer AVEED to another pharmacy, healthcare setting, prescriber, institution or distributor, except in the case where the transfer is to another certified healthcare setting (unique ship-to site address) where I am also the Authorized Representative.
- This healthcare setting must not dispense AVEED for home or patient self-administration.
- To make available to Endo Pharmaceuticals Solutions Inc. (Endo), and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the AVEED REMS Program.

## HEALTHCARE SETTING INFORMATION (\* REQUIRED FIELDS)

Healthcare Setting Name\*

DEA Number\* [On file with distributor account]

Address\*

City\*

State\*

ZIP\*

Setting Type:

Group practice

Independent practice

Institution

Other \_\_\_\_\_

Phone Number\*

Fax Number\*

Email Address

## AUTHORIZED REPRESENTATIVE INFORMATION (\* REQUIRED FIELDS)

M.D.

D.O.

Nurse

Physician Assistant

Practice Manager

Other \_\_\_\_\_

First Name\* (please print)

MI

Last Name\* (please print)

Title

Email Address\*

Phone Number\* Ext

Fax Number\*

Preferred Method of Communication\*

(please select **one**)

Email

Fax

I understand that this enrollment only applies to me as the designated Authorized Representative of this healthcare setting. I will complete a separate enrollment form for each healthcare setting (unique ship-to site address) for which my designation and responsibilities extend. Failure to enroll a healthcare setting and have certified healthcare providers in the AVEED REMS program will result in the inability to receive shipments of AVEED.

Healthcare Setting Authorized Representative Signature\*

Date\* [MM/DD/YYYY]