How Physicians Can Obtain Omegaven
(Revised May 8, 2013)

Note: many of these steps will occur concurrently so the prescriber should start submitting and not wait for a response to proceed to the next step:

1. You must arrange a supply of Omegaven prior to requesting an emergency IND from the FDA (do not actually purchase until you get your EIND).

Contact International Pharmacy in Hamburg, Germany. Fresenius typically won’t ship small orders and using this pharmacy is much easier if only obtaining for 1 patient. I am sure there are other international pharmacies that could also do this but this is who we have dealt with in the past. We are not endorsing them, it just the process we have followed. If you use International Pharmacy, however, they will NOT accept US credit cards. The preferred method of payment for them would be an international bank transfer or wire transfer to their bank account. They will submit the bank details by email directly to the customer. Checks are still a hassle as they might be lost, take weeks, or the conversion rate has totally changed in the meantime. Shipping is extra.

This is their link: http://www.pharmacy-international.de

Mrs. Rebecca Elvers
Export Sales
Pharmacy International
Hamburg (Germany)
Phone: + +49 40 41455961
Fax: +49 40 280 2518
Email: drugs@pharmacy-international.de

Once you place the order, they will email you when it is stock. Then you must call a courier to deliver it or have Pharmacy International ship it at an additional charge. International Pharmacy has several shipping options available.

2. After you have arranged a supply, please e-mail the following information to cder-dgp@fda.hhs.gov:

1. Requestor’s Name:
2. Sponsor’s Name (if different):
3. Name of Institution:
4. Address:
5. * Direct Phone Number:
6. ** Fax Number:
7. Email Address:
8. Drug Name:
9. Dosage Form:
10. Route of Administration:
11. Drug Supplier:
12. Are you requesting authorization to charge the patient (or the patient’s insurer) for the cost of the drug? (Y/N)
13. Provide a brief explanation of why charging is necessary:
14. Specify the cost per unit dose of the drug:
15. Charging is permitted to recover the cost of the drug plus shipping only. Do you agree? (Y/N)
16. Indication:
17. Dosing Regimen:
18. Patient ID (initials of patient):
19. Patient Sex:
20. Patient Race:
21. Patient Date of Birth:
22. Other therapies used in the patient for the indication:
23. Brief Clinical History (Information to support the diagnosis):
24. Any other information pertinent to patient, diagnosis, or indication:
25. Is the Physician familiar with the drug:
26. Please provide the most recent lab values (LFT’s), especially liver function values such as bilirubin (including Direct). Be sure to include dates on which lab was obtained. {Preferably a consecutive set of three values}

* It is imperative that a direct line to the sponsor be provided (not a general number) in the event there are questions. This will ensure timely fulfillment of the emergency request.
** You will be notified via fax whether the IND is granted. The IND # and regulatory reminders will be faxed to this number.

Note:

Soon the FDA will be involving the Division of Drug Information (DDI) to help answer questions regarding Omegaven. They can be contacted at Toll Free (855) 543-3784, or (301) 796-3400 druginfo@fda.hhs.gov

At this time, the FDA also provides an Omegaven questionnaire (outlined above) with instructions for obtaining an emergency IND or intermediate patient population (multipatient) IND. This questionnaire as well as FDA forms and processes are often updated, so DDI will soon play an important role in ensuring access to the most up-to-date information.
3. A physician at the FDA will evaluate your request and contact you if there are questions. If an emergency IND is granted, you will be given the IND number via fax. Provide this number to the Omegaven supplier and they will ship Omegaven to the sponsor or to an infusion pharmacy if you have made this type of arrangement. You should also provide a copy of the acknowledgement letter to the pharmacy or supplier you choose to use.

4. In addition, in order to satisfy requirements through the USDA, please refer to the information on the following website and provide it to the shipper and distributor to avoid the need for a veterinary permit:


Please note that a USDA import permit will not be required if the following is included in the shipping documents:
1. An identification of the material and the species of origin; and
2. A written declaration indicating the material does not include any equine, ruminant, swine or avian species or their materials (such as in transport media or stabilizers).

Next you need to get a veterinary registration with the USDA. Information on how to do this is posted at:

This information must be supplied as statements on producer/shipper letterhead in a clear and concise manner, and be available for review by the Inspectors at the Port of Arrival. We recommend that a separate memo or letter be included with the shipping documents, such as U.S. Customs declaration and invoice.

Please also refer to the following for more information on the responsibilities and paperwork you would need to submit to the Agency following the approval of your Emergency IND(s).

A searchable site of regulations can be found at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm

Instructions on completing 1571 and 1572 forms per 21 CFR 312.305(c)(5):
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm#form1571

5. Make sure to submit a copy of the protocol you plan to follow to your institution’s Investigational Review Board, including the informed consent form you plan to use.
Regulatory Responsibilities

Receipt of an IND is contingent upon your commitment to complete the regulatory requirements listed below:

1. An Emergency IND package including forms FDA 1571 and 1572 will be sent. The sponsor is responsible for the prompt completion and return of the forms.
2. The investigator may determine that the investigational use is considered emergency use of a test article qualifying for an exemption from prior IRB review. In this case, the investigator needs to notify the institutional review board within five working days of administering the test article.
3. FDA should be notified within 15 days of any serious and unexpected adverse experience and within 7 days of any fatal or life-threatening adverse experience associated with the use of the drug.
4. The submission to the FDA should include a clinical summary of the patient and a description of the investigational plan of drug use.
5. The sponsor is required to update FDA on an annual basis of the status of the investigational use.
6. Informed consent must be obtained from every subject prior to receiving the drug.
7. Following the issuance of an Emergency IND number authorizing the investigational use, the sponsor may contact the supplier of the drug product and inform them of his/her authorization to receive the drug. The sponsor may be able to obtain from the drug manufacturer information pertinent to the safe use of the investigational drug that may include, but not be limited to, an investigator’s brochure, a package insert, or some form of appropriate labeling.

You will receive an acknowledgement letter outlining the requirements and instructions for IND submission.

Omegaven – IND Application for Multiple Patients

If you are planning to enroll multiple children for Omegaven eIND use, you should write a protocol to be submitted to your IRB and to the FDA. Once the open protocol is approved by the IRB, FDA, and any other regulatory bodies required by your institution, you may withdraw the emergency use INDs and enroll the eIND patients onto the approved open protocol. Given that it takes time to write a protocol and obtain approval, you may continue to apply for emergency use INDs until the protocol is ready for patient enrollment. However, once the protocol is approved, you may then submit an annual report for the protocol, which would include all patients involved, as opposed to writing an individual annual report for each open eIND.

You may refer to 21 CFR 312.23 for IND content and format:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Any additional questions: Please contact:
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