CONSENT FORM
for participation in the
NUVIGIL® (armodafinil) / PROVIGIL® (modafinil) Pregnancy Registry Study

Study Title: **The NUVIGIL® (armodafinil) / PROVIGIL® (modafinil) Pregnancy Registry**
Study Sponsor: Cephalon, Inc. (a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.)
Study Number: C10953/9022
Call Center: 866-404-4106

Introduction

You are being asked to participate in the PROVIGIL (modafinil) and NUVIGIL (armodafinil) Pregnancy Registry study ("Registry") because you took PROVIGIL (modafinil) or NUVIGIL (armodafinil) during your pregnancy or you became pregnant within 6 weeks of receiving the drug.

This document explains the study: why it is being done, what kind of information will be requested, when and how the information will be requested, who to contact if you have any questions or concerns, as well as a description of any potential risks and benefits so you can make an informed decision about whether or not you want to participate.

Your participation is voluntary. You do not have to participate if you do not want to and you can withdraw your consent at any time. Your consent to participate can be provided over the phone after this document is read to you or by signing a copy of this form which will be mailed to you with a prepaid return envelope.

You do not have to make a decision today. You may ask additional questions at any time by calling the Registry at 866-404-4106 or by calling the sponsoring company. The sponsor of this study is Cephalon, Inc. (a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd.) who can be contacted by calling 800-896-5855.

The Registry study is being paid for by Cephalon, Inc. The Registry staff members collecting information for this study are being paid by Cephalon, Inc.

Schulman Associates Institutional Review Board, Inc. (Schulman) has approved the information in this consent document and has given approval for the sponsor to conduct the Registry. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the Registry. You must think about the information in this consent document for yourself. You must then decide if you want to participate in the Registry.

What is the purpose of this study?

NUVIGIL and PROVIGIL are medications approved by the United States Food and Drug Administration (FDA) to improve wakefulness in adults who experience excessive sleepiness from obstructive sleep apnea, shift work sleep disorder or narcolepsy. PROVIGIL was approved in 1998 and NUVIGIL was approved in 2007.

Since there are many women of child-bearing potential (that is, women who can become pregnant) who may be exposed to these products, and since there are no research studies in humans that show if these medications affect the development of a fetus (an unborn baby), the FDA required that the drug company conduct a study to evaluate the risks.

Therefore, the purpose of this study is to evaluate the safety of PROVIGIL and NUVIGIL during pregnancy. The study will collect information about your pregnancy and on your baby's health, growth and development up to 12 months of age.

This Registry is important because it will generate information that can be used by health care professionals to help treat and counsel woman who are exposed to the medications during pregnancy or women planning a pregnancy.

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What do I have to do to participate?

Participation requires your informed consent. In addition, in order for the Registry to obtain medical information about you and your baby from your health care providers your consent to release medical information to the Registry is also requested.

Your consent can be provided by signing this consent form and the medical information release form and sending them back to the Registry. Alternatively, you can provide consent over the phone after the both documents are read to you by Registry staff.

If you do not want to provide consent over the phone at this time, the following documents will be sent to you with prepaid return envelopes. You will receive 2 copies of this consent form and 2 copies of a medical information release authorization form that allows for medical information related to your pregnancy and your baby to be provided to the Registry.

Participation in this Registry has no impact on your ongoing care. You will not have to make any changes in the care already provided to you by your physicians or other health care providers. This study involves no experimental medications, procedures or tests. You will not have to make any extra office visits. You will not have extra tests or special treatments. You will not have to take any extra medications.

Your participation will last from the time you consent to 12 months after your pregnancy. You and your providers will be contacted approximately 7 times during the study; approximately once per trimester and around the time your baby is due. Information will also be collected when your baby is 6 and 12 months of age. All information will be collected by scheduled telephone interviews or by prepaid mail.

What kind of information will be provided to the Registry?

Registry staff will ask you and your health care providers to provide information about you, your health, past and present medical history, your pregnancy and about your baby's health.

You will be asked to provide the name and contact information of the doctor or other health care providers taking care of you during your pregnancy (like the obstetrician). After your baby is born, you will be asked to provide the name of your baby's doctor. If the Registry is not able to obtain information from your doctors or if you ask the Registry to not contact your doctors, you may be the only person asked to provide information to the Registry.

In addition, you will be asked to provide the name and phone number of a friend or relative who can serve as a back-up contact in case the Registry has trouble contacting you. Personal information will not be shared with the back-up contact and that person will be called only if you cannot be reached.

The Registry will obtain information from you and your doctors regarding your current pregnancy, the results of any prenatal tests and when you took PROVIGIL or NUVIGIL. In addition, the Registry will ask for your age, race, ethnicity, level of education, occupation, height, weight, the names and dates of other medications you take, your use of alcohol, tobacco, and recreational drugs. You and/or your doctors will be asked to provide your past medical history, the history of any previous pregnancies and about any other risk factors related to your pregnancy. Information will also be collected about the birth of your baby such as problems with delivery, infant status at birth such as length and weight and his or her status at 6 and 12 months of age. Information will also be requested if you did not have the baby.

How will the Registry keep my information confidential ?

You and your baby's medical information will be kept confidential within the limits of the law. The Registry will not reveal any information that identifies you or your baby by name to anyone outside of the Registry unless there is a medical or other emergency situation where the Sponsor or an authorized representative of the Sponsor has a duty or legal obligation to permit the inspection or review of study

related records that may identify you by name. This could include regulatory authorities such as FDA or European Union Regulatory Authorities, the Institutional Review Board (IRB) who is responsible for ethical oversight of this study or the Registry Advisory Committee (RAC) who is responsible for scientific oversight and data assessment. Therefore, absolute confidentiality cannot be guaranteed. If information from this study is published in a medical journal or presented at scientific meetings, you and your baby will not be identified.

All data obtained by the Registry will be entered into a secure study database. You and your baby will be identified by a unique subject ID number created upon enrollment. Your health care providers will use this ID number for your study records, which means that you will not be identified in the study database by name. However, due to the need to obtain and confirm information about the outcomes of your pregnancy and your baby's health from your health care providers, the Registry will need to collect information about you such as your name, date of birth, or medical record number to complete a medical information release authorization form. By providing your consent, your authorization and permission are given to the above-mentioned representatives to access your medical records for collection of data needed for the study.

How long does my permission last?

Your permission for your doctors and your baby's doctor to provide information to the Registry remains valid until the study has ended. A minimum of 200 participants will be asked to enroll into this Registry.

What are the possible side effects or risks of participating in this Registry?

There are no medical treatments or procedures required for this study. This study involves only the collection of information about you, your pregnancy and your baby's well-being and medical care. Therefore, the only risks are the potential emotional discomfort from answering some of the questions about your medical, family, pregnancy, and reproductive history.

Are there any benefits to taking part in this Registry?

There are no direct health benefits to you for being in the study. However, the information collected in the Registry may help other women like you who were exposed to PROVIGIL (modafinil) and NUVIGIL (armodafinil) during pregnancy or who become pregnant after receiving the PROVIGIL (modafinil) and NUVIGIL (armodafinil).

Will it cost me anything to take part in this Registry?

You will not have any additional expenses as a result of your participation in this Registry.

Will I be compensated for participating in the Registry?

No. There are no financial rewards for agreeing to give information to the Registry.

What if I decide not to participate?

Your participation in this Registry is voluntary. Your consent is required in order to participate. Your decision not to participate will not affect medical care provided to you or your baby. If you agree to participate but decide at a later date to withdraw your permission, you may do so at any time, for any reason, by contacting the Registry Call Center. The Registry will be allowed to use information about you and/or your baby up to the point that you decide to no longer participate.

Your participation in this Registry may end at any time if the Sponsor finds it necessary to limit or stop this study. This may occur without your permission; however you will be notified if this occurs.

Who can answer my questions about this Registry?

If at any time you have questions, concerns or complaints regarding this Registry, or to report adverse events or side effects you have several options.

- You can contact the Registry Call Center at 866-404-4106
- You can contact the sponsor drug safety department at 866-832-8537
- You can contact the sponsor's medical information department at 800-896-5855
- You are encouraged to report negative side effects of any prescription drug to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (800-332-1088).
- For questions about your rights while taking part in this study, you may call the Institutional Review Board (a group who reviews research programs to protect your rights) at 888-557-2472.

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Informed Consent

The Registry representative, whose name and signature will be printed below, has informed you about the nature of the PROVIGIL (modafinil) and NUVIGIL (armodafinil) Pregnancy Registry Study. You understand the purpose of this Registry and freely give your consent to participate, as described in this document. You have had an opportunity to ask questions. You have been informed that you will receive a copy of this consent form and the Medical Information Release Authorization Form.

Verbal Consent given by participant to Registry representative over phone on: _____
Date of Consent

_____
Printed Name of Registry Representative who reviewed the consent form with patient

_____ _____
Signature of Registry Representative Date Signed

_____ _____
Printed name of Registry Participant Date of Birth

_____ _____
Signature of Adult Registry Participant (or Assent for Participant who has not reached the Age of Majority) Date Signed

_____
Printed Name of Parent or Legal Guardian*

_____ _____
Signature of Parent or Legal Guardian* Date Signed

***By signing this consent document, I verify that I have the legal authority (legal custody) to give permission for this child to participate in this study.**

If I am the legal guardian of this child, I have provided copies of guardianship papers to the study doctor or designee.

To return a signed copy of the consent form, please use the prepaid envelope or mail to:

UBC
Attention: Call Center Manager
200 Pinecrest Plaza
Morgantown, WV 26505
866-404-4106 (call center)
304-554-3363 (fax)

To report adverse events directly to the sponsor:

Teva Branded Pharmaceutical Products R &D, Inc.
Attention: Pharmacovigilance Department
425 Privet Road, Horsham, PA 19044
866-832-8537
drug.safety@tevapharm.com

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