The NUVIGIL® (armodafinil) / PROVIGIL® (modafinil) Pregnancy Registry Informed Consent Form

TITLE:	Nuvigil® (armodafinil) Tablets [C-IV] and Provigil® (modafinil) Tablets [C-IV] Pregnancy Registry
PROTOCOL NO.:	C-10953-9022 IRB® Protocol #20211907
SPONSOR:	Cephalon, Inc. (a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.)
INVESTIGATOR:	Jessica Albano, PhD, MPH 301 Government Center Drive Wilmington, North Carolina 28403 United States
STUDY-RELATED PHONE NUMBER(S):	866-404-4106 (24 hours)

In this consent form, "you" always refers to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

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 six weeks of receiving either drug.

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. Whatever your decision is, there will be no penalty or loss of benefits to which you are otherwise entitled. 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 sent to you.

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 Pharmaceuticals USA, Inc.) who can be contacted by calling 800-896-5855.

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 childbearing 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 women who are exposed to the medications during pregnancy or women planning a pregnancy.

Since you have taken PROVIGIL® (modafinil) or NUVIGIL® (armodafinil) during your pregnancy or you became pregnant within six weeks of receiving either drug, we are asking you to be a part of this study, which collects information on women such as yourself. It is expected that the Registry will enroll a minimum of 200 participants.

The collection of the information and other activities related to this study will be performed by Registry Coordinating Center staff at Syneos Health, a research company who has been contracted by Cephalon, Inc. to conduct this Registry.

What do I have to do to participate?

Participation requires your informed consent. Additionally, the Registry requests your consent for release of medical information so we may obtain information about you and your baby from your health care providers.

Your routine health care will remain unchanged if you decide to participate in this Registry. 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 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 each document is 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. If mailed, you will receive two copies of this consent form and two 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. You will need to sign all forms. You will keep one copy of the consent form and one copy of the medical information release authorization form for your records. You will return a signed copy of each form to the Registry using the prepaid return envelope. Alternatively, you may receive these forms electronically by email where you will follow prompts to review and electronically sign each document. Once electronically signed, you and the Registry will receive an email with each of the signed forms.

Your participation will last from the time you consent to approximately 14 months after your pregnancy. You and your health care providers will be contacted approximately once per trimester and around the time your baby is due. Information will also be collected when your baby is six and 12 months of age. All information will be collected by scheduled telephone interviews, email, fax, or by prepaid mail.

If you breastfeed your infant, we will ask you to complete a short questionnaire when your baby is six and 12 months of age.

What kind of information will be given to the Study?

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, such as your obstetrician. After your baby is born, you will be asked to provide the name of your baby's doctor. If the Registry is unable 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, in order to give the Registry your contact information.

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, and 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 six and 12 months of age. If you choose to breastfeed, you will be asked to complete a short questionnaire when your baby is six and 12 months of age. Information will also be requested if you did not have the baby.

What is protected health information (PHI)?

Protected health information is information that is gathered by a health care provider, health plan or researcher that identifies you or which includes facts that may tie your identity to your health record. Protected health information includes:

- Information from your existing or future medical records that is needed for the PROVIGIL® (modafinil) and NUVIGIL® (armodafinil) Pregnancy Registry, as described in this informed consent form; ***and/or***
- Information about you that is created during the conduct of the PROVIGIL® (modafinil) and NUVIGIL® (armodafinil) Pregnancy Registry study, as described in this informed consent form.
- Examples of PHI, which may be collected, includes: demographic information (i.e. name, age, date of birth), results of physical exams, health histories and physicals, x-rays, patient diaries, questionnaires, records of treatments, and side effects of treatments.

How will the Registry keep my information confidential?

During this study, the Registry study will collect the information and data as described in this Consent form - your name, your baby's name, address, telephone number, and identifying information (such as medical record number or health plan number). The collection of this information is essential if you wish to participate in this research study. Data about you will be used by the authorized recipients for the purpose of this study and the research of the study medicines. All personnel accessing your data are required to respect your confidentiality at all times.

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 outcome 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.

Before the Registry staff sends any of your personal data outside of the Registry, your name or any other information that can identify you will be replaced by a code (for example, your initials and a random alphanumeric code), so that no-one outside the Registry will be able to find out that the data is about you. Only the Registry staff and some members of the sponsor will see your identifiable data at the Registry site. It is also possible that some government authorities and Ethics Committees (who check if the research study is safe for you) may need to see your identifiable data.

Person(s) or class of persons authorized to receive health information about you will include the Sponsor and its affiliates, agents/vendors, subcontractors, and representatives such as contract research organizations, laboratories, organizations that assist with the analysis of the data (including safety data) and similar agents, third party which will take part in the development of the study medicine].

The sponsor may have a duty or legal obligation to report certain safety information to the relevant authorities. 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. These governmental or other health authorities, the IRB/IEC, staff of Syneos Health and Cephalon, Inc. auditing group may inspect the Registry data files as permitted by law. Therefore, absolute confidentiality cannot be guaranteed.

If the Sponsor shares or discloses your information outside of the United States, it may be to a country with privacy laws that do not protect you at the same level as the U.S., however, the Sponsor will make every effort to ensure that your privacy remains protected by using appropriate safeguards to ensure protection and confidentiality of your data.

You may have certain rights under applicable law to access and correct your personal that is collected about you in order to correct errors, however, this right may be suspended during the research study to protect the integrity of the data. This right of access and correction can be exercised through the study doctor.

The sponsor may anonymize/de-identify personal data about you (for example, by aggregating data), in order to engage in further scientific/medical research and/or publication. By anonymizing or de-identifying your personal information, your data will not be linked with information that would allow any person or organization to determine that this information directly corresponds to you. If information from this Registry is published in a medical journal or presented at scientific meetings, you and your baby will not be identified by name or other personally identifying information.

The Sponsor will keep and process coded personal data for a minimum period of time which allows the Sponsor to make the necessary submissions to competent authorities related to the research or any potentially related situations, or as prescribed by applicable law. In all cases, these data are used by the Sponsor in a form that it cannot be identified back to you.

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.

You understand that collection, use and transfer of personal data (including your health data) about you as described in this form is necessary to do this study. Should you withdraw your consent to be in the study, no additional personal data will be collected about you, but the use of your personal data that was already collected before your withdrawal, remains lawful and may be used by the Sponsor to conduct the study and any future research, to meet its legal and regulatory obligations.

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 approximately 14 months after your pregnancy is over.

Risks and Discomforts

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 or discomforts that are expected are related to the possible loss of confidentiality and/or the emotional discomfort answering some of the questions about your medical, family, pregnancy, and reproductive history.

Benefits

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) or NUVIGIL® (armodafinil) during pregnancy or who became pregnant after receiving PROVIGIL® (modafinil) or NUVIGIL® (armodafinil).

Expenses

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

Payment for Participation

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

Alternatives
You may choose not to participate in this Registry.

Source of Funding
Funding for this research study will be provided by Cephalon, Inc.

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.

New Information
You will be told about new information that might change your decision to be in this Registry.

Questions
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 (24 hours) or you may let us know by sending a letter to the study at the address at the top of this informed consent form.
- 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 I-800-FDA-1088 (800-332-1088).

If you have questions about your rights as a research participant or if you have questions, concerns or complaints about the research, you may contact:

WCG IRB
Phone: 855-818-2289
E-mail: researchquestions@wcgirb.com

Protocol Identification number for this Registry: C-10953-9022

WCG IRB is a group of people who perform independent review of research. They help to protect the rights of people who are part of a research study.

WCG IRB may be unable to answer some Registry-specific questions; however, you may contact WCG if the Registry coordinating center cannot be reached or if you wish to talk to someone other than the Registry coordinating center staff.

Do not sign this consent form or give your verbal consent unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a copy of this informed consent form.

Informed Consent

- All pregnant or postpartum individuals, who are minors as recognized by their state of residence, are required to assent.
- Documentation of wet-ink assent is not required.

I have read the information in this consent form (or it has been read to me). The Registry representative from the Registry Coordinating Center, or my health care provider, whose signature is given below, has informed me about the nature of the PROVIGIL® (modafinil) and NUVIGIL® (armodafinil) Pregnancy Registry. I have had enough opportunity to ask questions. All my questions about the study and my participation in it have been answered. I freely consent to be in this Registry.

By giving informed consent, I have not given up any of my legal rights.

☐ Verbal consent given by Participant to Registry Coordinating Center staff over the phone on:
OR

_____
Date (dd/mm/yyyy)

☐ Informed Consent process conducted by Participant's health care provider on:

_____
Date (dd/mm/yyyy)

Signature of ☐ **Registry** Coordinating Center staff or ☐ Health care provider Date (dd/mm/yyyy)

Permission for a Patient who has reached the Age of Majority or Emancipated Minor to Participate in the Study

_____
Name of Participant Date of Birth (dd/mm/yyyy)

_____
Address of Participant

_____
Telephone number of consented Participant:

_____
Printed Name of Participant

_____ _____
Signature of Participant (optional) Date (dd/mm/yyyy)

If written informed consent is provided, please sign electronically or sign and return one signed original to Syneos Health at 301 Government Center Drive, Wilmington, North Carolina 28403 in the pre-addressed, postage paid envelope provided. Please keep one copy of this form for your own reference.

Permission for a Participant Under the Age of Majority to Participate in the Registry

As parent or guardian, I authorize _____ (participant's name) to become a participant in the Registry described in this form.

Relationship to Participant: _____

_____

For Participants Under the Age of Majority, Name of Parent/Guardian

_____

For Participants Under the Age of Majority, Address of Parent/Guardian

_____

For Participants Under the Age of Majority, Phone number of Parent/Guardian:

_____

For Participants Under the Age of Majority, Printed Name of Parent/Guardian

_____

For Participants Under the Age of Majority, Signature of Parent/Guardian Date (dd/mm/yyyy) (optional)

If written assent (by participant) and consent (by parent/guardian) are provided, please electronically sign or sign and return both signed originals to Syneos Health at 301 Government Center Drive, Wilmington, North Carolina 28403 in the pre-addressed, postage paid envelope provided. Please keep one copy of these forms for your own reference.