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"TESTING COMMUNICATIONS ON DRUGS PRODUCTS"
OMB Control No. 0910-0695

PROJECT CONFER: Comprehension of Over-the-Counter Naloxone for Emergency Response

(#16081)

TITLE OF INFORMATION COLLECTION: Naloxone Pilot Label Comprehension Questionnaire to Optimize the Drug Facts Label (Task 2)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

Prevention and treatment of opioid overdose is an urgent public health priority. One way that FDA is addressing this public health problem is by facilitating the development of nonprescription (OTC) naloxone, which is currently only available by prescription. FDA is implementing this through development of a model Drug Facts label (DFL) for an OTC naloxone. This DFL is to include all the information (other than information highly specific to a particular product) that a consumer would need to know to purchase naloxone appropriately, and to use naloxone in an emergency opioid overdose situation. This model DFL will then undergo label comprehension testing by an outside research organization. A pretested DFL with an acceptable level of consumer comprehension would then be available, and commercial sponsors could add their product-specific information to the DFL and conduct final consumer behavior testing. RTI International and Concentrics Research (referred to hereafter as the RTI-Concentrics team) will be partnering on this research study, each bringing to the project their unique expertise in working with vulnerable populations (RTI) and label testing (Concentrics). We will conduct this study in accordance with practices outlined in the FDA Guidance for Industry on Label Comprehension Studies for Nonprescription Drug Products (FDA, August, 2010).

This study is a comprehensive label comprehension testing program. There are three study tasks, the first of which was to conduct cognitive interviews to optimize the DFL. This application details procedures and materials for Task 2 adult all comers and users/associates only; we will seek separate approval for Task 2 adolescents and Task 3 as the procedures and materials will be informed by Task 2 study results.

The purpose of Task 2 is to conduct interviews to assess comprehension of pilot survey questions that will be asked during and to inform sample sizing for the pivotal study in Task 3 (referred to as 'methodology' hereafter). The interviews will be conducted with 18 potential end users of OTC Naloxone and 9 individuals representing a general population audience (N=27); see Section 3 for a thorough description of respondents. The RTI-Concentrics team will conduct Task 2 activities through partnerships with The Hazelden Betty Ford HBF (HBF) in Chicago, Illinois, an organization that provides substance abuse prevention and treatment services, and a professional recruitment firm in a location to be determined. Because the purpose of Task 2 is to obtain

feedback on the survey for the pivotal study, the sample is not intended to be nationally representative.

2. Intended use of information:

The study team will use the information they collect in Task 2 to inform the methodology for the Task 3 pivotal study.

3. Description of respondents:

The study population for Task 2 will consist of four user groups defined by FDA:

1. **Group 1 (n=9):** Adult prescription opioid users, including those in drug treatment programs, as well as family/friends of users who are not users themselves (i.e. associates).
2. **Group 2 (n=9):** Adult heroin users, including those in drug treatment programs, as well as their associates.
3. **Group 4 (n=9):** Adult all comers, including 30% low literacy general consumers and including some pregnant women.

Eligibility Criteria

Individuals will be included in the study if the following criteria are met. There are separate screeners for Groups 1 – 2 (Attachment A), and Group 4 (Attachment D) to assess eligibility.

Group 1 – Prescription Opioid Users & Associates (n=9)

1. Male or female, of any race

2. 18 years of age or older (to the extent possible, three participants will be aged 18-20 years old)
3. User: An individual who reports prescription opioid use in the past 30 days or is in treatment for prescription opioid use
4. Associate: An individual who does not report prescription opioid or heroin use in the past 30 days *and* is not in treatment for prescription opioid or heroin use *and* knows someone who uses prescription opioids or is in treatment for prescription opioid use.

Group 2 – Heroin Users & Associates (n=9)

1. Male or female, of any race
2. 18 years of age or older (to the extent possible, three participants will be aged 18-20 years old)
3. User: An individual who reports heroin use in the past 30 days or is in treatment for heroin use
4. Associate: An individual who does not report prescription opioid or heroin use in the past 30 days *and* is not in treatment for prescription opioid or heroin use *and* knows someone who uses heroin or is in treatment for heroin use.

Group 4 – All comers (n=9)

1. Male or female, of any race
2. 18 years of age or older (to the extent possible, three participants will be aged 18-20 years old)
3. Some participants must be pregnant

The screener for Groups 1 and 2 also collects ancillary data on prescription opioid and/or heroin use during the past 90 days and frequency of prescription opioid and/or heroin during the past 30 days to distinguish heavy from recreational users. The RTI-Concentrics team will use these data for analyses purposes only; they will not use medical records or samples in this study.

FDA has determined that at least 30% of the participants in all three groups)be of lower literacy. The study team will use two validated, single-item questions (Wallace et al., 2006; Morris et al., 2006)[1] in combination with responses to income- and education-level questions to assess for potential low-literacy at the initial screening for adults. The moderator from Concentrics

[1] During analysis, the study team will determine which validated item is most strongly correlated with Rapid Estimate of Adult Literacy in Medicine (REALM) score among adults; this item will be used as a literacy proxy for the pivotal study in Task 3.

Research will administer the validated Rapid Estimate of Adult Literacy in Medicine (REALM) to adults (Davis et al., 1993) to assess literacy on-site after consent but prior to conducting the study interview (see Structured Interview Guide in **Attachment E** for literacy assessments). Individuals excluded from the study due to their REALM scores will still be provided with the study incentive. The interviewer will tell them they were selected for a shorter version of the study so they will not know that they were excluded based on their REALM score (participants will not know they are taking the REALM; it will be presented as part of the interview).

Individuals will be excluded from the study if any of the following criteria are met.

1. Individuals who have been ordered by a judge to participate in treatment at the Hazelden Betty Ford Foundation.

2. The individual or anyone in their household is currently employed by any of the following (for Groups 1, 2, and 4)

    - A marketing or marketing research company
    - An advertising agency or public relations firm
    - A pharmacy or pharmaceutical company
    - A manufacturer of medicines
    - A managed care or health insurance company
    - A healthcare practice or hospital emergency room

3. The individual has ever been trained or employed as a healthcare professional (for Groups 1, 2, and 4).

4. The individual has participated in any clinical trial, product label study or marketing research study involving a healthcare product or topic in the previous twelve (12) months (for Groups 1, 2, and 4).

5. The individual cannot read, speak and/or understand English.

6. The individual normally wears corrective lenses, contacts or glasses to read and does not have them with him/her at the time of the interview.

7. The individual appears too impaired (e.g. under the influence of drugs or alcohol) at the time of the interview as observed by the study staff and incapable of providing consent or interpreting verbal or written instructions or materials. Overt signs of impairment include difficulty staying awake or 'nodding off', or unsteadiness (e.g., stumbling or swaying), or an inability to actively interact with study staff. All study staff received training on how to identify signs of impairment. If a participant exhibits any of these signs and/or the logistics coordinator or interviewer has other concerns about the participant's ability to participate in the study, the study team will terminate the interview process. The logistics coordinator will urge the participant to call a family member or friend to pick them up or to remain at the study site until they are no longer impaired. However, the study team cannot force the participant to remain on the premises if he/she does not want to.

Recruitment

Recruitment (and screening) procedures will vary by group. An overview of the process is shown in ***Exhibit 1***.

Exhibit 1. Overview of Recruitment and Screening Methods, by Group

Group	Recruitment Method	Screening Process
Group 1: Prescription opioid users/associates	HBF Online advertising Targeted community outreach Participant referral	Online Telephone
Group 2: Heroin users/associates	HBF Online advertising Targeted community outreach Participant referral	Online Telephone
Group 4: All comers	Recruitment firm	Telephone

Groups 1 and 2

As shown in Exhibit 1, adult users and associates representing Groups 1 and 2 will be recruited through a variety of mechanisms, each of which is described below.

HBF. Initially separate substance abuse treatment entities, Hazelden and the Betty Ford Center merged in 2014. They have 14 locations throughout the United States. The Chicago location serves adolescents, adults, and families through a variety of programs: Intensive Outpatient, Structured Sober Living, Teen Intervene, Family Program, Assessment and Evaluation, Continuing Recovery Care, and Recovery Management (http://www.hazeldenbettyford.org/locations/chicago). Participants will be recruited from all programs.

To ensure the study team can achieve the desired sample in the time allotted, they are implementing a multipronged recruitment strategy that assumes that the majority of interviews will be scheduled prior to data collection. They will do the following:

1. Provide HBF staff with a Provider Information Sheet about the study so they are aware of the organization's involvement and how they can be of assistance (**Attachment F**). In addition, they can use the Provider Information Sheet to inform their discussions with clients who may be eligible for the study.

2. Post study flyers throughout the facility (**Attachment G**). The flyer provides information about the study and contact information should they wish to be screened for eligibility.

3. Provide HBF staff with palm cards with details about the study to distribute to clients who express interest in participating in addition to placing them in client waiting areas (**Attachment H**).

The materials make it clear that the study is interested in recruiting associates, who may be family members or friends of HBF clients, in addition to users. They direct individuals to visit the study's website or to call the study's toll-free number to see if they are eligible.

Individuals who choose to access the screener online via the study's website will be presented with information about the study; told that they will be asked questions, some of which are about drug use (their own use and among people they know), to see if they are eligible to participate; that their responses will be kept private and that their contact information will be kept separately from their responses to the screener questions; and that they can choose not to answer any question and stop participating at any time (see **Attachment I** for the online screener). The script will also inform individuals that if they are eligible and wish to participate, they will need to provide their first name, email address, and/or phone number so study staff can send them a link to the online interview scheduler and remind them of their interview appointment. Finally, the introductory script will inform individuals that the interviews will be audio recorded and that members of the study team may listen to the interview by telephone. After reviewing this information, individuals will be asked to indicate their consent to be screened by selecting "next" which will advance them to the first screener question. If they do not wish to proceed, they will be instructed to close their internet browser. Aside from meeting the eligibility requirements outlined in Section 3, individuals must also agree to be audio recorded to participate in the study. Individuals who are eligible for the study based on their answers to the screening questions will be presented with an invitation script. The script will inform them that they are eligible for the study and that if there is space available, they will be contacted by email with a link to the online scheduler in the next 48 hours. They will be asked to provide their email address and telephone number if they would like to proceed with this step.

Designated RTI staff (i.e., RTI recruiters) will monitor online screener responses daily and determine which eligible participants to invite into the study. This determination will be made based on two factors:

1. *Established targets to ensure diversity in the sample in terms of group (i.e., Group 1 or 2), literacy level, and user vs. associate status.* If an individual is eligible, but the quota has been met for their particular segment, RTI will send them an email alerting them that they are on a waiting list and will be contacted if space becomes available.

2. *Limited risk of screening fraud.* It is possible that someone may complete the online screener more than once if they do not qualify for the study the first time. RTI will track IP addresses to help ensure that individuals who complete the screener more than once are not invited to take part in the study.

The RTI recruiters will send eligible individuals an email from the online scheduling system. They will be prompted to sign up for an interview slot in the preset schedule. The system allows a user to sign up for one slot only. The system will be set so that it only allows email addresses inputted by RTI recruiters to sign up for an interview slot, thus limiting the risk of non-screened individuals signing up an appointment. If the participant does not respond to the email within 48 hours, the RTI recruiters will initiate a follow-up contact through email and/or telephone to ensure the scheduling email was not diverted to their spam folder. We will contact individuals with scheduled interviews 1-2 days prior to their appointment for reminder purposes.

Individuals also have the option to call the study's toll-free telephone number for screening. RTI recruiters will field all inquiries from potential participants and screen those who are interested by telephone using a standardized screening process (**Attachment A**). The recruiter will introduce the study to potential participants and let them know that they will need to ask them sensitive questions about drug use, both their own use and among people they know, to see if they are eligible to participate; that their responses will be kept private and that their contact information will be kept separately from their responses to the screener questions; and that they can choose not to answer any question and stop participating at any time. RTI staff will inform them that if they are eligible and wish to participate, they will need to record their first name, email address and/or phone number so they can remind them of their interview appointment. Prior to asking them any questions, the recruiter will request their permission to proceed with the screening process. They will only screen those individuals who grant permission. The RTI recruiter will invite people who are eligible to participate in the study and schedule an interview should they wish to participate.

If RTI recruitment staff are unable to answer the phone, the caller will be asked to leave a message with his/her first name and telephone number so staff can call him/her back for screening purposes. The voicemail box will be password protected and only accessible to RTI staff responsible for screening potential participants.

Regarding associates, some will be exposed to flyers and palm cards placed at The HBF as they transport clients to and from clinic appointments, and others will learn about the study if they are attending a counseling session or other treatment activity with a HBF client (e.g., a husband may join his wife in one of their counseling sessions). Others may learn of the study through word of mouth (e.g., a HBF client may bring home a palm card and give it to their partner). The screening options and procedures are the same for Group 1 and 2 associates and users are the same.

HBF will receive a small stipend ($300) in appreciation of their time.

If study staff are unable to fully recruit for the data collection prior to the interview dates, or if there are last minute cancellations or no-shows, they may recruit additional participants by handing out flyers and palm cards at HBF.

Online Advertising. The study team will post advertisements online. The online advertisement provides similar details to what is included in the flyers and palm cards (**Attachment J**). Potential online advertising venues include the following:

- Craigslist: The study team will post the advertisement in the 'services' category.

- Facebook: The study team will post the advertisement on Facebook. They will focus on Facebook groups for people who use prescription opioids and/or heroin or who are in treatment for or in recovery from prescription opioid and/or heroin use (e.g., Heroin Addiction Support, Methadone Maintenance Treatment Support). They will request permission from group administrators to post study information

on the groups' pages if it is necessary to do so as some groups may be closed to non-members.

- Online forums: The study team will post the advertisement on online forums that target prescription opioid and/or heroin users or people in treatment for or in recovery from prescription opioid and/or heroin use (e.g., BlueLight, SoberRecovery). If necessary, they will request permission from forum administrators to post study information on the website.

Note that individuals recruited online will only have the option to be screened online, the procedures for which were described previously.

Targeted Community Outreach. The study team will identify appropriate venues for posting flyers and distributing palm cards to advertise the study. They will prioritize venues frequented by potential participants, such as public notice boards at libraries, community centers, and the like, and with permission, grocery and convenience stores, public health clinics, and area CBOs (e.g., harm-reduction organizations, drop-in centers).

Participant referral. Eligible individuals will be asked to mention the study to others in their social networks who may be interested in participating. This will occur in one of two ways depending on how individuals are screened. If eligibility is determined through online screening, individuals will be invited to refer others to the study when they receive the link to the online scheduler. If eligibility is determined by telephone, the RTI recruiter will convey the invitation to refer others to the study as part of the closing script. In both cases, the referral script makes it clear that referring others to the study is not a requirement for participation.

Group 4 (all comers)

The study team will work with a recruitment firm to recruit Group 4 participants (location to be determined). The facility will provide a 1-way mirror for FDA observation.

Recruitment firm staff will identify potential participants through their community partners and/or proprietary database and will contact them by telephone to assess eligibility using the Group 4 screener (**Attachment D**). They will schedule interview appointments with individuals who are eligible and interested in participating.

4. Date(s) to be Conducted:

Data collection for Task 2 will take place during a 4-6-week time frame after OMB and FDA RIHSC approval is received.

5. How the Information is being collected:

Task 2 is comprised of one-time, structured interviews to assess comprehension of the pivotal study survey questions that will be administered on a larger scale in Task 3. Concentrics staff will conduct the one-on-one interviews in person with participants. RTI and Concentrics Research will work in 2-person teams at each location. RTI staff will coordinate data collection

logistics and assess individuals for drug or alcohol-related impairment prior to checking them in. Concentrics Research staff will administer informed consent and the REALM test, conduct the interviews, and analyze and report on findings. All interviewers are experienced and qualified in cognitive interviewing methods. This is an interview study only; no drug will be administered or dispensed.

Group 1 and 2 interviews will take place in a private suite located in an office building near to HBF. When Group 1 and 2 participants arrive, study staff will provide the participant with the consent form that outlines the purpose and voluntary nature of the study. The interviewer will review the consent form with participants and provide them with an opportunity to ask questions (**Attachment M**). If the Concentrics moderator has concerns about an individual's understanding of the consent form due to potential literacy issues, she will end the interview without telling the participant that they were disqualified (see script as part of **Attachment A**) and the participant will still receive the reimbursement.

Individuals will be required to provide written consent to be in the study (first name only). Prior to beginning the interview, the moderator will let the participant know if members of the study team are listening to the interview by telephone. If the participant objects, the moderator will disconnect the telephone line before proceeding with the interview. On the other hand, if an individual conveys to the moderator that they do not wish to be audio recorded when they present for the interview, they will be dismissed and will not be given the reimbursement. This condition of participation was explained during screening, and the individual had an opportunity at that point in time to decline being audio recorded in which case, they would have been ineligible to participate.

Participants who sign the consent form will next undergo a literacy assessment administered by Concentrics staff. The interviewer will use the REALM for this purpose (**Attachment E**). FDA has requested that approximately 30% of participants be of lower literacy defined as a REALM score of 60 or below for adults. If someone does not meet the literacy requirement, Concentrics staff will end the interview without telling the participant that they were disqualified and the participant will receive the full incentive.

Following the literacy assessment, the Concentrics interviewer will give the participant the naloxone DFL (**Attachment P**). The interviewer will leave the room to give the participant the opportunity to review the DFL at his/her own pace. The DFL will be a similar size and shape to a possible commercial package. Once the participant indicates he/she is finished reading the DFL, the moderator will return to the room and begin the interview (see **Attachment E**). The moderator will present a series of 3rd-person overdose scenarios each of which will be followed by a closed-ended question that requires the participant to make a judgement about what to do next (e.g., give the 1st dose, call 911). After providing a response, the moderator will ask the participant to explain his/her answer which will enable the research team to assess comprehension of the survey questions as well as DFL instructions. There will also be time at the end of the interview to probe on issues that arise during the discussion.

The risk of participation in an interview is minimal. Although the study team does not anticipate that this will be an issue based on their experiences with Task 1 and the nature of the interview questions, they have developed processes for handling impairment or distress:

- Impairment: If an individual is too impaired to participate, the study team will terminate the interview process and request that he/she call a friend or family member to pick them up or remains at the study site until they are no longer impaired. The study team, however, cannot force them to follow through with these measures.

- Distress: We will give the individual the telephone number for a mental health crisis line near to the study location.

The study team will audio record the interviews. RTI staff will also take notes during the interviews held at the professional recruitment firm (Group 4 all comers) to record nonverbal cues and behaviors (e.g. apparent participant confusion or difficulty in evaluating the labeling) to accompany the final audio-recording. Total interview time will be 45 minutes, which includes time to administer the REALM and informed consent).

Once the interview is completed, RTI staff will provide the participant with a monetary token of appreciation. Participants will receive the equivalent of $50 . Note that study staff will provide participants with their tokens of appreciation even if they withdraw from the study or are unable to participate if the literacy requirements are not met. Section 7 provides justification for the incentive amounts.

After the data collection is complete at all locations, the audio-recordings will be transcribed and the study team will create a summary report of the observations and insights from the interviews.

6. Confidentiality of Participants:

During screening, it will be necessary to collect the first names, email addresses, and phone numbers from individuals who are willing to participate and have scheduled an individual, in-person interview appointment (through the online screener or verbally). This personally identifiable information (PII), which will be recorded separately from the screener (see **Attachments A-2 and D-2**), will be used to remind individuals of upcoming appointments. The screener and the form that records PII will be stored separately in a locked file cabinet in the project director's office and destroyed at the end of the study.

RTI will assign each participant a unique study identification (ID) number during the screening process to protect privacy, and they will record the ID number on each page of the screener so this information can be linked to participants' interview responses (the interview guide also includes a field for the study ID number, but no PII). However, the study ID number will not be recorded on the contact information form; therefore, it is not possible to link screener or interview responses to PII which is only recorded on the contact information form.

Linking participant's interview data to some of the screening data is essential for analysis and interpretation of findings. For example, FDA needs to know if there are differences in label comprehension across (heroin vs. prescription opioid users) and within groups (users vs. associates) and by key demographic characteristics (e.g., education level, race/ethnicity, or

gender) to determine whether and how to revise the label and/or survey questions to improve comprehension and the validity of the findings from the Task 3 pivotal survey.

Other data from the screener will be used by RTI to inform Task 2 recruitment procedures and study procedures for Task 3. For example, the screener includes two proxy questions for health literacy: "How confident are you in filling out medical forms by yourself" and "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?". These questions need to be asked in the screener because it is not possible to administer the REALM (literacy) test over the telephone. Given the study requirements for low literacy representation, these proxy questions will be used to try to predict which participants will turn out to be low literacy. If these questions are not predictive of literacy level, the study team will need to identify an alternative method for Task 3 to avoid possible time and overrun costs to the study.

Participants will be identified only by study number in the data file that RTI gives to Concentrics. This means that Concentrics cannot link the data to participants' contact information. For online screening only, the study team will track the IP addresses of system users to reduce the possibility of screening fraud. The list of IP addresses will be kept separately from screener data and contact information and destroyed at the end of the study.

For Groups 1 and 2 the study team will also use codes to indicate user groups and whether a participant is a user or an associate as an additional safeguard—i.e., rather than referring to "heroin users and associates" study staff will code them as "Group 2- either "R" (for user) or "E" (for associate). Participants will not be told which group they are part of (participants will not be aware that there are separate groups and what the eligibility requirements are). No PII will be shared with FDA.

The study team will audio record the individual, in-person interviews for the purpose of verifying the interview notes, and the recordings will be stored on password-protected computers at RTI, Concentrics Research, and FDA. The audio recordings will be destroyed at the end of the study. All data will be reported to FDA in aggregate; the study team will remove extraneous variables from the data file before delivering it to FDA (e.g., screener questions that are not pertinent to describing the sample or are unrelated to eligibility criteria).

7. Amount and justification for any proposed incentive (token of appreciation)

Monetary incentives are intended to recognize the time burden placed on participants, encourage their cooperation, and convey appreciation for their contributions to the research. Incentives help ensure that sufficient numbers of participants can be recruited to participate in the data collection. Research has shown that monetary incentives improve response rates (Ryu et al., 2006; Singer et al., 1999), thus it is likely that without the incentive as an inducement, more people would need to be screened to achieve the desired cooperation rate, thus increasing the burden hours and overall time needed to complete data collection activities.

The incentive amount for participants will be equivalent to $50; this amount is somewhat lower relative to other FDA studies. The goal was to select an amount that would be attractive to

participants, but was not so large as to appear coercive, which is a consideration when conducting research with vulnerable populations (Festinger et al., 2005).

8. Questions of a Sensitive Nature

As describe previously, screening entails sensitive questions about individuals' drug use and drug use among people they may know which is necessary to determine eligibility. None of the label comprehension pilot interview questions for Task 2 are of a sensitive nature. As previously described, the focus of these interviews is to assess comprehension of the survey questions that will be administered in the Task 3 pivotal study. As part of the informed consent procedures, interviewers will explain to participants that they do not need to answer any questions that make them feel uncomfortable and can stop participation at any time. To ensure cultural competence, all interviewers participated in a cultural sensitivity training led by an expert in the area of illicit opioid use and working with this vulnerable population.

9. Description of Statistical Methods

Concentrics Research will use transcribed audio files, interview notes and participant screener data and demographics when summarizing findings for this study. They will summarize screener and demographic data in aggregate format with no personally identifiable information in table and text formats to describe study participants. All of the data collected by the study team is qualitative; thus, they plan to conduct a thematic analysis of all data.

Concentrics Research will organize analyses around the major topics included in the interview guides. Staff trained in quantitative and qualitative analysis methods will work together to prepare an analysis plan and review the data. All analyses will be data-driven. The analysis team will meet periodically to discuss findings and overall themes, as well as recommendations for the Task 3 survey. They will summarize the data into a final report with quotations from the interviews provided as examples to emphasize key findings.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Participant	No. of Participants	Participation Time (minutes)	Burden (hours)*
Screener: Group 1	45	5	4
Screener: Group 2	45	5	4
Screener: Group 4	60	5	5
Interview (n=9 per group)	27	45	27
Total	**177**	**5-50 minutes**	**40**

Note: *The study team estimates that they will need to screen 150 participants to obtain 27 completed interviews for Task 2 for an annual burden of 40 hours. For Group 4, they expect they will need to screen 60 individuals to obtain 9 participants due to the requirement to include some pregnant women. They anticipate that they will need to screen a smaller number of participants to complete 9 interviews each for Group 1 (n=45) and 2 (n=45) given the targeted, multipronged recruitment approaches.*

REQUESTED APPROVAL DATE: June 2017

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FDA CENTER: Center for Drug Evaluation and Research

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