
From: Presley, Denver
Sent: Thursday, October 07, 2010 5:28 PM
To: 'Perraut, Andrew B.'
Subject: Resubmission: CFSANs " Real Time Food Recall survey,"
Importance: High

Drew:

As a result of your recommendations in the July 12, 2010 conference call with CFSAN regarding the subject survey,

the center has consulted with CDC and modified the survey as noted below. The center is ready to officially resubmit

the revised survey and are providing an advance copy in case you have comment. Also, per that conference call ,

the ICR was to be retracted but I note it is still pending at OMB. Assuming the overall revised survey ICR is in compliance

with your recommendations, CFSAN is anxious to .resubmit, pending the retraction process. The identifying information

for the previous ICR submission is attached below.

Thanxs

Denver Presley

FDA-PRA Program

301-796-3793

Denver:

During our conference call on July 12, 2010, OMB requested that CFSAN 1) consult with CDC on our proposed Real Time Food Recall Surveys project, then 2) revise the Real Time Food Recall Surveys ICR to request a new generic clearance. CFSAN has consulted with CDC and revised the ICR, including the questionnaires. Attached please find the revised ICR and all supporting documents. Also, please note that a cover note written by Linda Verrill is below. Would you please forward this e-mail, the cover note, and the attachments to Drew?

Please let us know if you have any questions

Thank you,

Anne

Drew,

Thank you for your review of FDA's Real Time Food Recall Surveys request for generic approval.

To refresh your memory, FDA is seeking generic clearance for a bank of survey questions that can be employed immediately after the onset of a foodborne illness outbreak or food recall, when FDA surrounding a foodborne illness outbreak or food recall is particularly complex and wants to ensure consumer awareness of the information and that consumers are taking appropriate precautions. FDA plans to use an online consumer panel to administer the surveys.

During the telephone meeting between OMB as FDA on July 12, 2010, OMB asked FDA to consult with CDC on the proposed project. The consultation, detailed in the attached revised supporting statement, led to some changes in the instruments and in the survey administration strategy.

One important outcome of the consultation between FDA and CDC is CDC's strong recommendation for FDA to shorten the amount of time between realizing the need for a survey and survey administration. To that end, FDA has developed some draft surveys with questions that do not contain blanks for the food and pathogen. They are examples of food/pathogen pairings that can be repeated using all known food/pathogen pairings, if needed, prior to OMB clearance for this project.

Another important outcome of the consultation between FDA and CDC is that FDA has learned that CDC has a bank of questions that have OMB preapproval. The questions comprise CDC's Health Message Testing System (HMTS) (OMB Control # 0920-0572). This approval is for 9,000 burden hours for a bank of 325 questions preapproved for use by any CDC Center, Division, or Branch for telephone, intercept, and cognitive interviews, focus groups and online surveys with an external audience. As long as users adhere to the guidelines, no further OMB review is needed before survey administration. The goal of the HMTS is to test health messages for clarity, salience, appeal, and persuasiveness. Most of the pre-approved questions must be used verbatim; with the exception of questions such as the following: Is [*Insert health topic or behavior*] a topic on which you seek out information? If so, how? More information on the HMTS is available at [Http://intranet.cdc.gov/nchm/dhcm/mcsb/HealthMessage.html](http://intranet.cdc.gov/nchm/dhcm/mcsb/HealthMessage.html).

CDC has another bank of questions that have OMB preapproval, these for website usability testing (OMB Control #0920-0847). FDA believes there is a parallel between CDC's preapproved question banks and FDA's request for approval for the Real Time Food Recall Surveys; FDA and CDC's joint objective

of ensuring that our efforts to communicate with the public are clear, salient, and are reaching the target audience.

Thank you very much for reviewing our resubmission. If you would like to talk further about the package, please contact Denver Presley to arrange another phone conference.

Thank you,

Linda Verrill

Linda Verrill, Ph.D.
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The following files are attached:

1. Clean ICR Supporting Statement Part A
2. Clean ICR Supporting Statement Part B
3. ICR Supporting Statement Part A (tracked changes showing)
4. ICR Supporting Statement Part B (tracked changes showing)
5. Synovate E-panel invitations (OMB requested a copy of this)
- Surveys:
6. Generic Food Recall Survey
7. "All clear" Generic Food Recall Survey
8. Spinach Food Recall Survey
9. "All clear" Spinach Food Recall Survey
10. Tomato Food Recall Survey
11. "All clear" Tomato Food Recall Survey
12. Bagged Cut Lettuce Food Recall Survey
13. "All clear" Bagged Cut Lettuce Food Recall Survey



Clean ICR
Reporting Statement



Clean ICR
Reporting Statement



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