Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions:

Surveys of Pharmacists and Patients

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

In 2013, generic drugs made up 86% of all human prescription drug prescribing.[1] While generic drugs are proven to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts, they are not required to be the same in appearance. In fact, a brand drug's appearance may be considered to be the intellectual property of the brand-name manufacturer, a type of "trade dress" (like a trademark) that ensures that generic products differ in appearance from branded medications. Generic drugs may differ substantially from their brand-name therapeutic equivalents and from each other in their physical appearance (e.g., color, shape, size, or markings). This leads to a situation in which therapeutically equivalent products from different manufacturers appear different.

Research has shown that patients use pill appearance to help them figure out which pills to take at which times.[2,3] Patients may use pills to ensure that they're still getting the same medication made by the same manufacturer. Alternatively, differences in appearance between therapeutically equivalent drugs may lead to patient confusion when they receive a refill for a chronic medication that differs in appearance from the prior medication.[4,5]

---

[1] IMS Institute for Healthcare Informatics. Medicine use and shifting costs of healthcare: a review of the use of medicines in the United States in 2013. April 2014.

[2] Lenahan JL, McCarthy DM, Davis TC, et al. A drug by any other name: patients' ability to identify medication regimens and its association with adherence and health outcomes. *Journal of Health Communication*. 2013;18 Suppl 1:31-39.

[3] Cohen MR, Smetzer JL. ISMP medication error report analysis: Oral solid medication appearance should play a greater role in medication error prevention. *Hospital Pharmacy*. 2011;46:830–834.

[4] Engelberg AB. The case for standardizing the appearance of bioequivalent medications. *Journal of Managed Care Pharmacy*. 2011;17(4):321-323.

[5] Greene JA, Kesselheim AS. Why do the same drugs look different? Pills, trade dress, and public health. *New England Journal of Medicine*. 2011;365:83-89.

Changes in drug appearance when pharmacists switch generic drug suppliers, for example, may result in patient confusion and concerns about a generic drug's safety and efficacy . This may cause patients to change or discontinue their medication, which could lead to harmful clinical and public health consequences as well as increased health care costs if patients are avoiding generic drugs. Changes in drug appearance may also result in confusion and safety and efficacy concerns by health care providers about a generic drug product.

The FDA recognizes that physical attributes may affect patient opinions of and experiences with drug products. In December 2013, the FDA published a draft guidance recommending that ANDA applicants make their generic oral tablet products of similar size and shape to the reference listed drug for comparable ease of swallowing and for patient acceptance of and compliance with treatment regimens.[6] However, the extent to which differences in appearance between bioequivalent products create patient confusion, affect patient medication adherence, or are handled by pharmacists is currently unknown. Therefore, we intend to conduct surveys of pharmacists and patients about their experiences resulting from generic drug product pill appearance to further our understanding of issues related to generic drug appearance.

2. Purpose and Use of the Information Collection

This project will conduct a survey of pharmacists and two surveys of patients regarding their perspectives on and experiences with generic drugs that differ in appearance from previous refills of the same medication, which may occur when pharmacies switch drug suppliers. The goals of the pharmacist survey are to provide insight into the frequency with which a nationally representative sample of pharmacists must manage issues that arise with patients whose otherwise routine refills of generic drugs involve changes in the physical characteristics of the pills, the strategies they use to notify patients of changes in appearance, and what outcomes they observe in patients' confidence in and continued use of essential medication regimens prescribed by their physicians. The goals of the patient surveys are to provide insights into the beliefs about and experiences with changes in the appearance of generic chronic medications of patients with chronic conditions. The topic areas are similar to that of the pharmacist survey, but provide more direct assessment of patient beliefs and outcomes that may not be reported to a health care provider. Patient surveys will also allow for assessments of the relationships among patients' demographic characteristics, patients' beliefs about pill appearance, and patients' outcomes related to changes in pill appearance.

Since part of FDA's mission is to ensure the safe use of prescription medications, it is important to understand potential concerns surrounding dispensing and use of generic medications. One concern that may affect the safe use of generic drugs is the variations in appearance of those drugs among generic manufacturers. These surveys will elicit information on the existence and extent of problems caused by changes in pill appearance and will further our understanding of

[6] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. Guidance for Industry: Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules. Draft guidance. December 2013.

the relationships between changes in pill appearance and patient outcomes such as non-adherence. In addition, the investigation of factors that explain the associations among changes in pill appearance and various patient outcomes will help in identifying factors that could be modified to improve the safe and effective use of generic medications. The results from these surveys will be used by FDA to determine steps that need to be taken to promote safe use of generic medicines with varying appearances, to inform the development of policies and educational programs that may need to be undertaken, and may help identify areas for further research.

Each survey includes several topics to elicit information from the respondents on generic drugs and their appearance. The pharmacist and patient surveys contain parallel topics, but questions will be targeted toward the respective audience. Topics covered in the two patient surveys are similar. Specific topics addressed in each survey are listed in Table 1.

Table 1. Survey Topics

Pharmacist survey	**Patient surveys**
Demographic information	Demographic information
Background information on pharmacy volume and pill appearance changes	Patient recognition of pill appearance changes, and uses of pill appearance consistency
Preferences regarding pill appearance changes	Preferences regarding pill appearance changes
Pharmacist confidence in the bioequivalence of generic drugs	Patient confidence in the bioequivalence of generic drugs
Pharmacist involvement in managing changes in pill appearance	Observations of pharmacist involvement in managing changes in pill appearance
Observations of patient confidence in the safety and effectiveness of pills that have changed in appearance	Patient confidence in the safety and effectiveness of pills that have changed in appearance
Observations of patient outcomes related to changes in pill appearance	Patient outcomes related to changes in pill appearance

All of the surveys begin with a series of questions on the respondent's confidence in the bioequivalence of generic drugs. Prior surveys have found that some consumers express concerns about whether generic drugs are clinically equivalent based on their misperceptions about the bioequivalence requirement or lack of knowledge about the FDA approval process and oversight.[7,8] Asking about perceptions of bioequivalence will allow for the identification of whether such beliefs are common among respondents and whether there are patterns in the demographic characteristics that are associated with these beliefs. This section will provide background and context for the interpretation of responses from later sections related to the

[7] Keenum AJ, Devoe JE, Chisolm DJ, et al. Generic medications for you, but brand-name medications for me. *Research in Social and Administrative Pharmacy*. 2012;8(6):574-578.

[8] Shrank WH, Cox ER, Fischer MA, et al. Patients' perceptions of generic medications. *Health Affairs*. 2009;28:546-556.

changes in appearance of generic drugs. It will also serve as a way to introduce the topic, since changes in pill appearance are specific to generic drugs.

In addition to questions on the bioequivalence of generic drugs, the pharmacist survey contains a set of questions specific to narrow therapeutic index (NTI) drugs. NTI drugs are those for which small differences in dose or blood concentration may lead to therapeutic failures or adverse drug reactions. In the pharmacist survey, there is a series of questions specific to NTI drugs that also addresses confidence in the bioequivalence of NTI generics, involvement in managing changes in pill appearance for NTI generics, observations of patient confidence in the safety and effectiveness of NTI pills that have changed in appearance, and observations of patient outcomes related to changes in pill appearance for NTI drugs. This section will provide information on whether pharmacists and their patients respond differently to changes in appearance among different categories of pills by focusing on a group of medications for which appropriate use and adherence is critical for maximum therapeutic effectiveness and safety.

A summary of the surveys is provided in Table 2 for clarity in the subsequent sections.

Table 2. Summary of Pharmacist and Patient Surveys

Survey	**Method of contact for the survey**	**Contractor**	**Sub-contractor conducting the survey**	**Target number of respondents**
Pharmacist	Mail (electronic submission optional)	Team of researchers at Brigham and Women's Hospital/Harvard Medical School	Nielsen	1000
Patient #1	Telephone		Nielsen	1000
Patient #2	Mail (electronic submission optional)		Optum	1000

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of some information for this study. The pharmacist survey will be conducted by Nielsen via traditional mailing. Pharmacists will have the option to complete the survey online and therefore submitting electronically, or to mail back their responses. Similarly, one of the patient surveys will be conducted by Optum via traditional mailing. Patients will have the option to complete the survey online and therefore submitting electronically, or to mail back their responses. Both the Nielsen pharmacist survey and Optum patient survey afford participants the option of submitting their responses electronically but will not force them to do so, ensuring that participants who are less comfortable with new technologies feel comfortable taking part in the survey. Based on the subcontractors' prior experiences, it is estimated that 20% of the respondents will complete the survey electronically. Burden will be reduced by requesting data for each respondent on a one-time basis and by keeping surveys to 20 minutes or less.

4. Efforts to Identify Duplication and Use of Similar Information

The contractors conducted an environmental scan of the peer-reviewed medical literature (using the PubMed and EMBASE databases) and trade/professional literature to identify published surveys addressing perceptions by patients and health professionals (particularly pharmacists) about brand-name and generic drugs and their perceptions of the physical characteristics of prescription drugs. The contractors conducted a series of successive searches, reviewed the titles and/or abstracts of the hits from those searches, and then read the full articles of the studies that appeared to meet the entry criteria. In addition to the articles, the contractors sought to obtain the actual survey instruments, contacting the article's corresponding author if necessary.

The contractors identified 21 articles describing surveys addressing patient and professional perceptions about brand-name and generic drugs. The majority of these surveys found variability in whether patients preferred generic drugs or whether patients were confused by generic substitution. Patients generally did not dispute the cost-effectiveness of generic substitution and did not view generic drug use negatively. Some patients experienced anxiety with new use of a generic drug, but the majority of patients viewed generic substitution or generic drug use positively.

Of the 21 surveys identified, 7 addressed pill appearance as a secondary topic of interest. Some of these studies found that confusion was caused by the name, color, shape, or taste of pills.[9,10] One study found that color and shape are less frequently used methods of identifying generic pills than trade name.[11] A few of these surveys also examined what pharmacists thought about label changes.[12,13] None of the identified surveys examined the preferences of patients and pharmacists as to pill appearance or the positive or negative impact of pill appearance changes on medication adherence, two primary goals of our investigation. Since there were no duplicative surveys or other research work that included many of the pre-identified data elements needed to address the specific question of generic drug appearance, we determined that survey instruments needed to be developed and conducting new surveys would be necessary to gather this information.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

---

[9] Toverud EL, Røise AK, Hogstad G, et al. Norwegian patients on generic antihypertensive drugs: a qualitative study of their own experiences. *European Journal of Clinical Pharmacology*. 2011;67(1):33-38.

[10] Schumaker LL, Bond VA. Antiretroviral therapy in Zambia: colours, 'spoiling', 'talk' and the meaning of antiretrovirals. *Social Science and Medicine*. 2008;67(12):2126-2134.

[11] Yelland MJ, Veitch PC. How do patients identify their drugs? *Australian Family Physician*. 1989;18(11):1441-1445.

[12] Chuang MH, Wang YF, Chen M, et al. Effectiveness of implementation of a new drug storage label and error-reducing process on the accuracy of drug dispensing. *Journal of Medical Systems*. 2012;36(3):1469-1474.

[13] Zargarzadeh AH, Law AV. Design and test of preference for a new prescription medication label. *International Journal of Clinical Pharmacy*. 2011;33(2):252-259.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of October 15, 2014 (79 FR 61872). Comments submitted raised several issues pertaining to the proposed collection of information. We summarize the comments and provide our responses below:

(Comment 1) Two comments expressed concerns related to trade dress protection issues, noting that the requirement that generic products differ in appearance from the Reference Listed Drug is well established in case law. A pill's physical appearance can qualify as trade dress, protected under the Lanham Act, which functions to distinguish between products from different manufacturers. A drug's physical appearance can also be considered a protected form of non-verbal expression under the First Amendment. If required to change the appearance of their medications, the generic industry would face additional development costs.
(Response) The purpose of these surveys is to gather information on the awareness of patients and pharmacists about changes in the appearance of medications, the frequency with which changes in appearance occurs, strategies that pharmacists use to inform patients when the appearance of their medications changes, and the outcomes associated with these strategies. The results of the surveys will be used to inform the development of patient education about differences in pill appearance and inform the development of education for pharmacists on strategies to counsel patients when the appearance of their medications changes. The purpose of these surveys is not to reverse existing legal precedents, require the generic drug industry change the appearance of their medications, or support the infringement of intellectual property, First Amendment, or any other legally protected interests.

(Comment 2) One comment mentioned that the term "pill" is used in the Federal Register Notice to describe oral solid dosage forms such as tablets and capsules, but is defined by Merriam-Webster much more narrowly to exclude tablets and capsules, which has the potential to create confusion.

(Response) Because the FR notice is seeking opinions from the public, we used language accessible to the general public. To avoid confusion, the word "pill" is defined in the introduction of each survey instrument to clarify its meaning, with the statement that the word "pill" includes both tablet and capsule dosage forms.

(Comment 3) One comment mentioned that the survey findings may be used by FDA to guide pharmacy business practice, which is the jurisdiction of the State Boards of Pharmacy.
(Response) As stated earlier, the purpose of these surveys is to gather information on the awareness of patients about changes in the appearance of their medications, the frequency with which changes in appearance occurs, strategies that pharmacists use to inform patients when the appearance of their medications changes, and the outcomes associated with these strategies. The results of the surveys will be used to inform the development of patient education about differences in pill appearance and inform the development of education for pharmacists on strategies to counsel patients when the appearance of their medications changes. FDA does not intend to, itself, guide pharmacy business practices.

(Comment 4) One comment expressed concern that confidential patient information from an insurance database will be identified and shared with Federal Government employees, which may violate HIPAA regulations.
(Response) These surveys received approval from the Institutional Review Board (IRB) at the academic medical center where the survey is being conducted, which was accepted by FDA's IRB (Research In Human Subject Committee). IRB approval ensures compliance with human subjects' protection laws, including HIPAA. No FDA personnel will have access to any identifiable patient information.

(Comment 5) One comment suggested that instead of conducting the study, FDA should data mine an internal source of data (product complaints received from pharmaceutical companies, healthcare providers, and consumers) to gather information on potential confusion and medication mistakes.
(Response) The proposed study focuses on patient and pharmacist experiences and outcomes associated with changes in pill appearance, a topic of which patient confusion and medication mistakes are only a part. Although some medication mistakes and patient confusion data may be captured in our internal database (FDA's Adverse Event Reporting System), the specific data sought from the proposed study do not exist in this database.

(Comment 6) One comment suggested that if the information on potential confusion and medication mistakes cannot be found in current databases, FDA should request that pharmacy school students conduct this study and publish results in a peer-reviewed journal to assure transparency and reduce government spending.
(Response) High-quality surveys require substantial resources that would likely not be available to pharmacy students for class projects. These surveys are being conducted by an academic medical institution that has expertise in conducting surveys of patients and health care providers, which will provide high-quality and valid data and assure transparency. The results will be published in a peer-reviewed journal(s) and will be made publicly available.

(Comment 7) One comment mentioned that these surveys will collect data on pharmacist and patient perceptions, which may not correlate to actual use data and thus may not provide meaningful information on safe and effective use of generic drugs or yield substantial evidence to support adoption of any regulatory policies. The comment noted that further investigations will be needed to understand how pharmacist and patient perceptions translate to actual practices and effects, and encouraged FDA to consider comments to docket 2013-N-1434 in considering what further work will be needed and the level of evidence needed to support any regulatory policy changes.
(Response) These surveys include questions on patient and pharmacist perceptions, as well as their actual experiences and behaviors as they relate to generic drugs and changes in drug appearance. The survey findings will be used to inform the development of patient education about differences in pill appearance and inform the development of education for pharmacists on strategies to counsel patients when the appearance of their medications changes.

(Comment 8) One comment noted that if this study is conducted, the surveys should be carefully crafted to collect useful data using validated, well-developed methodology and assumptions. The comment requested the opportunity to review the proposed surveys and to submit additional survey questions.
(Response) Well-established survey methods are being used in the development and conducting of this survey. The survey questions were carefully crafted according to published guidelines for survey question development[14,15] and were further refined by an expert panel that included individuals with pharmacy-related professional backgrounds and patient representatives. The survey instruments will undergo cognitive testing and formal pre-testing to ensure questions are clear and answerable, and that study results are valid and useful. A copy of the draft surveys have been provided to the commenter.

(Comment 9) One comment noted that the variations in the physical appearance of drug products may help pharmacists and patients avoid confusion, facilitate detection of counterfeit drug products and serve pharmacovigilance purposes by providing information about the source of a specific product. Variation in pill appearance can also serve to notify patients that the source of their medication has changed. FDA should acknowledge the ways in which differences in pill appearance are beneficial when determining whether and how to conduct the survey.
(Response) The focus of these surveys is on identifying patient and pharmacist concerns and problems related to changes in pill appearance, with the goal of informing the development of future patient and provider educational interventions and programs to address identified problems. However, it is acknowledged that changes in the physical appearance of medications could have both negative and beneficial effects. Therefore, questions have been added to gauge how changes in pill appearance may benefit pharmacists and patients.

---

[14] Woodward CA. Questionnaire construction and question writing for research in medical education. Med Educ 1988;22:345-63.

[15] Fitzpatrick R. Surveys of patient satisfaction: II—Designing a questionnaire and conducting a survey. BMJ 1991 302(6785):1129-1132.

(Comment 10) One comment commended FDA for planning this study. The commenter was also pleased that FDA plans to conduct two separate patient surveys to ensure that a broad and relevant patient experience is reflected in the results.
(Response) We thank this commenter for the support of our study and agree that conducting two separate patient surveys will improve the validity and generalizability of the results.

9. Explanation of Any Payment or Gift to Respondents

Pharmacist Survey: Pharmacists invited to complete the survey will receive a $5 honorarium included in the first mailing. The contractors have found that honoraria are extremely important in recruiting a sufficient sample of health professionals to provide survey responses about work-related topics, and this is confirmed in numerous independent studies.[16,17] Thus, the contractors anticipate offering the pharmacists in the sample a token $5 honorarium, based on the final sample size and budgetary constraints. If available in the budget, non-respondents may receive an additional $1 at the final (4-week) mailing.

Patient Survey #1: There will be no honorarium or other gift for invited patients in the patient survey conducted by Nielsen. It would be difficult to implement an honorarium for respondents of a phone survey, and Nielsen's standard practice for telephone surveys is to not offer respondents an honorarium.

Patient Survey #2: The patient survey conducted by Optum will include a $5 honorarium to all invited participants in the initial mailing. Participants who complete the survey will receive an additional $20 gift card. A total of approximately $25 is Optum's standard honorarium for a patient survey. Based on Optum's prior experience, they decided in conjunction with the contractors that it was cost efficient for this study to utilize a $5 pre-incentive along with a larger post-incentive to promote a higher response rate.

10. Assurance of Confidentiality Provided to Respondents

All surveys: The introductions to each survey state that participation is voluntary. Partners Human Research Committee, Brigham and Women's Hospital's IRB, reviewed and approved this project, which includes all three surveys, on January 15, 2014. Subsequent amendments have been approved by the IRB. Once approved by OMB, the final survey instruments will be submitted to the IRB as a final amendment.

---

[16] David MC, Ware RS. Meta-analysis of randomized controlled trials supports the use of incentives for inducing response to electronic health surveys. *Journal of Clinical Epidemiology*. 2014;67(11):1210-1221.
[17] Edwards PJ, Roberts I, Clarke MJ, et al. Methods to increase response to postal and electronic questionnaires. *Cochrane Database of Systematic Reviews*. 2009;(3):MR000008.

Neither the contractors nor the FDA will gain access to or see personally identifiable information for any of the three surveys.

Pharmacist Survey: Privacy will be maintained by the use of anonymous questionnaires. For the pharmacist survey, a mailed questionnaire was chosen rather than a telephone survey or an email survey because it is easier to guarantee respondent anonymity using an impersonal, mailed questionnaire with no individual identifying information. Basic demographic information is the only personal information requested from the respondents. The survey will contain a coded numeric identifier to assure that duplicate on-line and paper surveys are not received and to allow for follow-up reminders to be sent to those who have not completed a survey. The key for this coded identifier will be kept by Nielsen via their normal protocol, not shared with the data design/analysis team at Harvard Medical School/Brigham and Women's Hospital, and will be destroyed after the closure of the study response time period.

Pharmacist Survey and Patient Survey #1: Nielsen maintains a privacy policy that applies to its activities, including the pharmacist survey and one of the patient surveys for this project. All employees are required to sign confidentiality agreements upon joining Nielsen, and are required to certify, on an annual basis, their compliance with the Code of Ethics, which also contains provisions protecting client information. Nielsen conducts criminal background checks for all employees prior to hire by Nielsen. Nielsen maintains a number of security policies and standard operation procedures, copies of which can be provided to clients or potential clients upon the execution of a confidentiality agreement. Client information is stored on Nielsen's servers, secured by Windows / Linux file permissions access with failed attempts being logged. Nielsen has deployed Symantec EndPoint Protection on all laptops, which ensures that all hard drives are encrypted. Whenever Nielsen receives any customer lists (or any other personally identifiable information) for use in connection with a market research study, Nielsen requires that such information be sent via a secure method (*e.g.*, FTP site or encrypted email attachment) and such information is stored in a secure environment. Nielsen also conducts due diligence on all of its vendors, and requires that they sign comprehensive agreements containing stringent confidentiality and data security requirements. Nielsen will provide de-identified survey responses to the contractors, who will perform data analysis and interpretation to answer the research questions solely with de-identified survey data. Nielsen will securely dispose of identifiable survey data after completion of the study.

Patient survey #2: Optum will link patients selected for the survey in their de-identified research data with their internal database that contains identifying information including the patient's address. Optum will manage the survey collection process, including covering survey administration and data aggregation costs. Optum maintains privacy of patient records at all times. Only limited Optum staff and the survey vendor staff associated with the distribution of patient surveys, will receive patient identifying information. The survey vendor will sign a confidentiality agreement, and will follow standard operating procedures (SOPs) which are consistent with Guidelines for Good Pharmacoepidemiology Practices (http://www.pharmacoepi.org). Optum will provide the contractor with aggregate data results

in a written report, and will work with contractor in the interpretation of results. Optum will securely dispose of identifiable survey data seven years after completion of the study.

In addition, Optum will submit a protocol, survey, and supporting documents for the web/mail survey to the New England IRB and Privacy Board for review and approval prior to initiation of the study.

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The survey instruments are provided in Appendices 1 (pharmacist survey), 2 (patient survey #1), and 3 (patient survey #2).

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this one-time collection of information is 1,017 hours. These estimates are based on the contractor's and subcontractors' experience with previous surveys of patients and healthcare professionals.

Table 3.--Estimated Annual Reporting Burden [1]

Surveys of pharmacists and patients on variations in the physical characteristics of generic drug pills and patients' perceptions	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per Response	Total Hours
Pharmacist surveys mailed[2]	2,161	--	--	--	--
Pharmacist pretests	9	1	9	0.333 (20 minutes)	3
Pharmacist survey completes	1,000	1	1,000	0.3 (18 minutes)	300
Patient #1 survey calls	5,000	--	--	--	--
Patient #1 surveys screened	3,330	1	3,330	0.033 (2 minutes)	111
Patient #1 surveys eligible	1,200	--	--	--	--
Patient #1 survey pretests	9	1	9	0.333 (20 minutes)	3
Patients #1 survey completes	1,000	1	1,000	0.3 (18 minutes)	300
Patient #2 surveys mailed[2]	2,000	--	--	--	--
Patient #2 survey completes	1,000	1	1,000	0.33 (18 minutes)	300

Total	--	--	--	--	1,017

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Eligibility is determined prior to mailing out the surveys, so screening is not required.

Burden will be reduced by recording data on a one-time basis for each respondent, and by keeping surveys to no more than 20 minutes for any respondent, with an estimated average burden of 18 minutes per respondent.

Pharmacist survey: Based on an 11% undeliverable rate and a 52% response rate, 2,161 questionnaires will be mailed to pharmacists to obtain the 1,000 responses sought.

Patient survey #1: Based on the 20% estimated response rate, 5,000 individuals will be called to obtain the 1,000 responses sought. Of these 5,000, we estimate that 3,330 will agree to undergo brief screening questions, which will identify approximately 1,200 eligible participants. Of those eligible, we anticipate that 1,000 will complete the survey.

Patient survey #2: Based on a goal response rate of 50%, 2,000 surveys will be mailed to patients in order to obtain the 1,000 responses sought.

12b. Annualized Cost Burden Estimate

Table 4. Estimated Annual Cost Burden

Surveys of pharmacists and patients on variations in the physical characteristics of generic drug pills and patients' perceptions	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Survey of Pharmacists	303	$56.01[1]	$16,971.03
Survey of Patients #1	414	$19.98[2]	$8,271.72
Survey of Patients #2	300	$19.98[2]	$5,994.00
Total			$31,236.75

[1]Based on the mean annual wage for pharmacists, May 2013, as reported by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes291051.htm)
[2]Based on the median weekly earnings of $799 for U.S. wage and salary workers, fourth quarter 2014, as reported by the Bureau of Labor Statistics (http://www.bls.gov/news.release/archives/wkyeng_01212015.pdf)

13. Estimates of Other Total Annual Costs to Respondents and/or Record Keepers/ Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for this collection of data is $1,372,145 ($457,382 per year for 3 years). This includes costs paid to the contractor to conduct an environmental scan of available surveys, create the survey instruments, design the survey and sampling methods, sub-contract with survey research organizations when deemed necessary for survey implementation, analyze the survey results, and provide a report to the FDA ($749,892 contract for pharmacist survey and patient survey #1, $542,253 contract addition for patient survey #2). The cost also includes FDA staff time to attend progress meetings, provide input on the study design and methodology, review interim deliverables, and interpret the results for dissemination ($80,000; 10 hours per week for 3 years).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for survey data will be used to analyze the data, such as descriptive statistics, bivariable analyses, and regression models. See Section B for detailed information on the design, hypotheses, and analysis plan. The contractors and FDA anticipate disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, publications, articles, and posting on FDA's website.

The estimated timeline for the project is presented in Table 5.

Table 5. Estimated Project Timetable

Task	Estimated Completion Date
60-day FR notice publication	October 15, 2014
30-day FR notice publication	May 2015
OMB Review of PRA package	July 2015
RIHSC review	Completed
Cognitive testing and pretesting	September 2015
Survey administration/data collection	March 2016
Data analysis	June 2016
Draft report to the FDA	August 2016

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.