2004 Continuation of National Surveys of
Prescription Drug Information Provided to Patients

Supporting Statement

A. Justification

ABSTRACT: Since 1982, the Food and Drug Administration (FDA) has collected data about health professional counseling of patients regarding prescription medications, distribution of written information, and patient-initiated information-seeking. The survey used was designed to be a tracking study, to be repeated periodically to assess national changes and trends over time. Data were collected in the fall of 1982, 1984, 1992, 1994, 1996, 1998, and 2001 *(OMB approval #0910-0279). There are several reasons it is essential for the FDA to continue to conduct this survey in 2004. Section 601 of Title VI of Public Law 104-180 set target goals for the distribution and quality of written medication information received by patients when new prescriptions are received at the pharmacy and requires the development of "a mechanism to assess periodically...the frequency with which the [oral and written] information is provided to consumers." Specifically, by the end of 2006, 95% of people are to be given such information. In addition, FDA is responsible for assessing progress toward a national health objective within the Healthy People 2010 policy initiative to increase patient counseling regarding prescription drug medications. Current permission to conduct the survey expires in June 2004; however, since healthcare information can vary seasonally, we have striven to conduct the tracking survey over the years during the fall-winter season for consistency. Therefore, extension of the clearance to allow FDA to continue to carry out this tracking survey in autumn-winter 2004 is necessary in order to determine progress toward the objectives.*

A1. Necessity for the Information Collection

As many as half of patients taking medicines deviate significantly from their prescribed regimens, increasing the utilization of medical resources such as nursing homes, hospitals, physician visits, and unnecessary treatment (Office of Inspector General, Medication Regimens: Causes of Noncompliance, 1990). There are many reasons for this widespread problem of drug regimen adherence, but a large part of the problem can be traced to inadequate knowledge on the part of patients about how to use

medicines properly. Furthermore, patients need information on drug precautions, contraindications, and side effects. If properly informed, patients may be better able to avoid adverse reactions and interactions (Lakshmanan et al, 1986), and to better recognize and interpret side effects, allowing for quicker remedial action. The Inspector General's report states that "Education is the key to improving compliance. Strategies to improve compliance include physicians and pharmacists better educating patients about their medication regimens. Effective counseling by the physician and pharmacist may be the single best intervention for patients with compliance problems" (p. ii).

Under the Federal Food, Drug, and Cosmetic Act (the act) FDA has the duty to assure the adequate labeling of prescription (Rx) drugs. Under section 502(a) of the act, 21 U.S.C. ?352(a), a drug product is misbranded if its labeling or advertising is misleading in any particular, and under section 201(n) of the act (21 U.S.C. ?321(n)), a drug's labeling is misleading if its labeling or advertising fails to reveal material facts (attachment A). To assure that Rx drugs are not misbranded, for certain drugs FDA has periodically asserted that adequate labeling requires information for patients. In 1982, when the FDA revoked a planned initiative to require mandatory patient package inserts for Rx drugs in favor of private sector initiatives in this area, FDA indicated that it will periodically conduct surveys to evaluate the availability of adequate patient information on a nationwide basis (attachment B).

To obtain data on the nature and extent of prescription drug information received by patients, the FDA has been conducting a periodic survey of patients who had recently obtained new prescriptions, begun in 1982 and continued in 1984, 1992, 1994, 1996, 1998, and 2001. The survey assessed the extent to which verbal and written drug information was received from pharmacists and physicians. In addition, patients were asked a series of questions about their willingness and ability to seek out drug information from health professionals and other sources. The survey was designed to be a tracking study, to be repeated periodically to assess changes and trends over time.

The survey is conducted by telephone on a national random sample of adults age 18 and over who received a new prescription for themselves or a household member within the past 4 weeks. The interview assesses the extent to which oral and written information was received from the doctor, the pharmacist, and other sources. Respondents are also asked attitudinal questions, and demographic and other background characteristics are also obtained.

Several factors make it essential to continue to repeat this survey at the current time. Section 601 of Public Law 104-180 requires that 75% of patients receiving new prescriptions be given useful written medication information by the end of 2000, with a 95% level to be achieved by 2006. This law also directs the development of "a mechanism to assess periodically...the frequency with which the [oral and written prescription] information is provided to consumers." (attachment C). In addition, FDA has responsibility for tracking and implementing a national health objective under the national Healthy People 2010 initiative, which calls for a 95% level of useful prescription medication counseling for patients from physicians or pharmacists by the year 2006. (attachment D.) Therefore, we need to continue conducting

the survey to have current information to ascertain progress and direct further planning toward these goals.

A2. Uses of the Information

The data obtained in this tracking survey of patients' receipt of information about prescription drugs are used by FDA to carry out its responsibility to ensure the dissemination of accurate information about regulated products to the public. This survey has provided data essential for tracking national progress toward meeting the objectives for providing useful Rx medication information to patients specified in the Department of Health and Human Services Healthy People 2010 and now mandated legislatively through P.L. 104-180 Title VI (see section A1).

A3. Use of Improved Information Technology

Burden will be minimized by collecting information by a CATI system (Computer Assisted Telephone Interviewing) directly into a computer. There will be no forms for respondents to complete, skip patterns are automatically followed, and response entry is much less subject to error. This will be a one-time telephone call only, with no further callbacks following interview completion.

A4. Efforts to Avoid Duplication

The studies planned for 2004 is designed to repeat the survey conducted by FDA in 1982, 1984, 1992, 1994, 1996, 1998, and 2001 to examine trends over time and to understand the current nature and extent of prescription drug information received by consumers. No other existing survey provides this tracking data. No duplication of this kind of tracking survey in relation to prescription drug information for consumers has occurred.

A5. Impact (if any) on Small Business and Methods Used to Minimize Burden

This collection of information does not involve small businesses or similar entities.

A6. Consequences If This Information Collection Was Not Conducted or Conducted Less Frequently

If this information was not collected, it would significantly hamper FDA's ability to measure national progress toward mandated levels of prescription drug information provided to patients. Regular biannual collection of this information is needed to keep current our understanding of the problems and

needs of the nation's medication consumers to provide direction to professional, public, and private sector efforts.

This survey is not a frequently recurring information collection. Originally, data were tracked over a 2-year time interval (1982-1984) with an 8-year lag between the 1992 data collection and the one prior to that in 1984. During the interval, many changes in the health care system occurred that affected information received by patients. In addition, legislation occurred, particularly the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), which required pharmacists to offer to counsel Medicaid patients about prescription drugs. The lack of empirical information about the actual levels of information patients were receiving between 1984 and 1992 hampered FDA's efforts to plan directives for patient information and to provide direction to the professional and private sectors, because our understanding of the problems and needs of patients failed to reflect the most recent developments. Thereafter, the survey was conducted every two to three years.

There are no technical or legal obstacles to reducing burden as specified in A5.

A7. Special Circumstances

1) *Requiring more than quarterly respondent reporting:* Not applicable, as the respondent reports only one time.

2) *Requiring written respondent reporting in fewer than 30 days:* Not applicable, as the survey is conducted entirely by telephone. No written response is required.

3) *Requiring submission of more than an original and two copies of any document:* Respondents are not asked to submit any documents.

4) *Requiring respondents to retain records longer than three years:* Respondents are not asked to retain any records.

5) *Conducting a survey that is not designed to be generalizable to the universe of study:* This survey is designed to be generalizable to the universe of study. In order to allow generalizability, the survey is conducted with a national random sample of households (see section B2).

6) *Requiring the use of non-OMB-approved statistical data classifications*: This survey does not use data classifications not approved by OMB. Standard categories for data classification are used for collecting demographic data in the questionnaire as approved by OMB in 1998.

7) *Including confidentiality pledges or data security policies not supported by legislative or regulatory authority or impeding of data sharing with other agencies:* The survey does not require

individual identifiers. FDA receives the data from the contractor in a format that does not identify respondents. There is no impediment to sharing the data.

8) *Requiring respondents to submit proprietary trade secrets:* There are no requirements for respondents to submit trade secrets.

A8. Outside Consultation

1) *Federal Register Notice and Comments*

Following the procedures for review, the FDA has sent a notice forward describing the Agency's request for continuation of this information collection and soliciting public review and comment, which was published in the Federal Register on Tuesday, January 27, 2004. One public comment was received, from the National Council for Patient Information and Education (NCPIE), a consortium of several hundred professional, consumer, and industry associations, and the comment expressed a favorable opinion of continuing the survey and useful to the Council of the survey results.

2) *Consultation with Persons Outside the Agency*

The project was originally developed in conjunction with major health professional associations, such as the National Association of Boards of Pharmacy, the Joint Commission of Pharmacy Practitioners, and the American Society of Hospital Pharmacists.

In addition, results of the surveys have been shared with the National Council for Patient Information and Education, a key nongovernmental group consisting of approximately 250 medical, pharmacy, drug industry, consumer, and other organizations (including the American Medical Association, American Nursing Association, the American Pharmaceutical Association, the Pharmaceutical Manufacturers Association, and the Consumer Federation of America), whose goal is to stimulate patient education program development. NCPIE was represented on the committee that determined the Healthy People 2010 objectives, including the evaluation of oral medication counseling received by patients, and we have presented the results of our surveys regularly at NCPIE national meetings and to many of their member organizations..

A9. Payments or Gifts to Respondents

There are no payments or gifts to respondents.

A10. Confidentiality

Respondents will be assured at the outset of the interview that their answers will remain anonymous. There is no need to collect respondent names since no follow-up activities are to be carried out as part of this study, therefore neither respondent names nor personal identifiers will be obtained as part of the survey. Contact identifiers will not be released by the contractor to the government.

A11. Sensitive Questions

There are no sensitive questions that raise privacy concerns, such as sexual behavior/attitudes or religious beliefs.

A12. Hour Burden

The only respondent burden will derive from the time needed to listen to and respond to the survey questions, which will occur on a one-time basis.

The length of the screener portion of the survey is estimated at 2 minutes, and the full survey length is estimated at an additional 19 minutes. The response burden chart that follows shows the projected annual burden. For the **2001** survey, **15,319** potential respondents needed to be contacted to obtain 1,000 completed interviews. Thus, for the screener, the estimated annual burden is **306** hours, and for the full questionnaire the estimated annual burden is **320** hours. The total estimated annual burden hours are **626**.

Estimated Annual Reporting Burden: Screener"					
Year	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2004	15,319	1	15,319	02	306
Total					306

*There are no capital costs or operating and maintenance costs associated with this collection.

Annual Reporting Burden: Survey*					
Year	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours

Annual Reporting Burden: Survey*					
2004	1,000	1	1,000	.32	320
Total					320

*There are no capital costs or operating and maintenance costs associated with this collection.

A13. Costs to Respondents

There will be no costs incurred by respondents.

A14. Costs to Government

The cost of data collection and data processing will be $115,000.

A15. Changes in Burden

The change is due to the increasing number of people who need to be screened in order to get the required number of people who met the screening criteria (18 years of age or older, having received a prescription medicine in person within the previous 4 weeks, etc.). In 2000, we estimated 9,643 people needed to be screened based on the number that needed to be screened in the 1998 survey. But the actual number that needed to be screened in 2000 turned out to be 15,319, so for the 2004 (current) supporting statement, I used the number of 15,319 to base the estimate of screening burden. That's why the burden hours increased, but only from 606 to 626 because the only change is in the number who need to be screened, not the number who get the full questionnaire.

A16. Tabulation, Publication Plans, and Schedule

Tabulation and analysis: The statistical analyses will follow the same procedures used for the earlier surveys so that the evaluation of trends over time can have matching input. Data will be subjected to descriptive analyses, primarily through the use of frequencies, with cross tabulations of the knowledge, attitude, and behavior variables by demographic factors. Additional multivariate analyses will be performed to evaluate whether or not subjects received specific types of information, how users of various information channels differ along demographic and other characteristics, and the influence of demographic and other subject characteristics on willingness to seek medication information. Patterns

of attitudes toward seeking information will be examined with factor analysis, and patterns of information-seeking strategies will be examined using cluster analysis.

Publication: The results of the surveys are reported to the FDA Commissioner and to professional, industry, and consumer groups through presentations and the professional literature, as with previous surveys. (Citations from earlier surveys include: Morris, Tabak, and Gondek, "Counseling Patients About Prescribed Medication: 12-Year Trends," *Medical Care* 35:10, 1997; Morris et al., "A Survey of Patient Sources of Prescription Drug Information," *American Journal of Public Health*, 74:10, 1984; Morris et al., "A Segmentational Analysis of Prescription Drug Information Seeking," *Medical Care*, 25:10, 1987. FDA also provides selected results of the surveys on the Internet. The URL is: http://www.fda.gov/cder/ddmac/Y2KTITLE.HTM

Schedule. Following OMB approval, the contractor will draw the sample, conduct the survey, and prepare the report and other deliverables in accordance with the contract. Total estimated time for completion of the survey is 12 weeks. Data collection will take place in fall-winter of 2004 to be consistent with the previous surveys, thus avoiding seasonal bias.

A17. Approval Not to Display OMB Expiration Date

We are not seeking approval to not display the OMB expiration date. The OMB approval number and expiration date will be displayed on the questionnaires.

A18. Exemptions to Certification Statement

We are not seeking any exemptions to the certification statement listed in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

The questionnaire is attached (attachment F).

B1. Respondent Universe and Sample Selection

Potential respondents are adults (18 years or older) in the continental United States who have obtained one or more new (non-refill) prescriptions at a pharmacy for themselves or a member of their household in the last four weeks and were present when the medicine was prescribed. Screening criteria also include speaking English or Spanish. The research will be undertaken through an existing FDA contract with a survey research organization (Market Facts, Inc.) for quick-response data collection.

A final sample of 1,000 completed interviews is required to match the sample sizes of the earlier surveys. This size will provide a level of precision of plus or minus 3%, which would provide accurate estimates within the population.

B2. Procedures for the Collection of Information

The surveys are conducted using a nationally representative sample of telephone numbers generated from a sampling system from GENESYS, the in-house sampling system Synovate leases from MSG, Inc. GENESYS generates each random telephone number through a single-stage sampling process in which all telephone numbers have an equal probability of selection, whether listed or unlisted. GENESYS produces efficient samples by generating random numbers within randomly selected blocks known to contain at least two listed numbers. The advantage of beginning with blocks containing a known residential number is that it avoids generating numbers in blocks that are assigned exclusively to businesses or are unassigned.

The resulting sample of telephone numbers is one in which all telephone numbers, whether listed or unlisted, have an equal probability of selection. Sample preparation continues by matching the generated sample against a file of all published business numbers in the U.S. This allows the removal of known business numbers from the sample and increases the efficiency of telephone interviewing.

Within each household, eligible respondents are identified. If the household contacted has more than one adult aged 18 or over, the adult who answers the telephone is interviewed, provided they meet the other screening criteria for eligibility.

B3. Procedures to Maximize Response Rates

In the 2001 survey, the contractor implemented several steps to maximize response rates. Every telephone number in the sample that could potentially reach a respondent (this does not include disconnects, business numbers, faxes, modems, etc.) received up to 25 attempts to reach a respondent. Call-backs were scheduled during different times of the day and days of the week, including weekends, to increase the chances of locating an available respondent. In addition, interviewers scheduled appointments to complete surveys at times requested by respondents. A Spanish-speaking interviewer re-contacted respondents who spoke only Spanish.

Follow-up attempts were conducted in cases of initial refusal or respondents who terminated the interview before it was finished. These interviews were conducted by more experienced, specially

trained interviewers. In addition, pre-notification letters prior to follow-up attempts were sent to initial refusals or quits for whom an address match was available through a tele-matching service. The pre-notification letters seem to have had a positive impact on respondent cooperation. Overall, the efforts to increase response rate appear to have had a positive effect and will be continued in the 2004 administration.

In the 1996 administration of this survey, an effort was made to check on the possibility of non-response bias by conducting a brief survey among 73 non-respondents who had indicated they did not wish to participate in the study after being asked twice. There were no significant differences in the demographic profiles of the survey participants and non-respondents. We did not continue this procedure in 1998 and 2001.

B4. Tests of Procedures

A pilot test will not be necessary. The same survey form used in the earlier administrations will be used in 2004 to be able to continue tracking responses to the same items.

B5. Contacts

The data will again be collected by Synovate, with a task order under FDA's quick-response contract. As this is a repeat survey and analyses will be exactly the same as on the previous surveys, no additional statistical plans or consultations have been made. The data will be analyzed by the Division of Surveillance, Research, and Communication Support in FDA's Office of Drug Safety. The contact individuals are Ellen Tabak, Ph.D., Project Officer (telephone 301-827-7843) and Leigh Seaver, Ph.D., Vice President, Synovate, (703) 790-9099 ext. 103.

REFERENCES

Lakshmanan M.C., Hershey C.O., Breslau D. Hospital admissions caused by iatrogenic disease. *Arch Intern Med* 1986;147:1931-1934.

Office of the Inspector General. *Medication Regimens: Causes of Noncompliance.* 1990.

ATTACHMENTS

A: FD&C Act, Section 201 (n) and Section 502(a)

B: Federal Register, vol. 47, no. 173, September 7, 1982

C: Public Law 104-180

D: Healthy People 2010 Objectives for Medical Product Safety

E: PoSelected Data Results from Previous Surveys

F: Federal Register , vol. 69, No. 17, January 27, 2004.