agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Sandra Gambescia, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.* Written comments should be received within 60 days of this notice.

Proposed Project

National Blood Lead Surveillance System (OMB No. 0920–0337) — Extension — National Center for Environmental Health, Centers for Disease Control and Prevention. CDC, National Center for Environmental Health began the National Childhood Lead Surveillance Program in 1992. The goals of the childhood lead surveillance program are to: (1) Establish childhood lead surveillance systems at the state and national levels; (2) use surveillance data to estimate the extent of elevated blood-lead levels (BLLs) among children; (3) assess the follow-up of children with elevated blood-lead levels; (4) examine potential sources of lead exposure; and (5) help allocate resources for lead poison prevention activities. State surveillance systems are based on reports of blood-lead tests from laboratories. Ideally, laboratories report results of all lead tests (not just elevated values) to the state health department; however, each state determines the reporting level for blood-lead tests. In addition to blood-lead test results, state child-specific surveillance databases contain follow-up data on children with elevated blood-lead levels including data on medical treatment, environmental investigations, and potential sources of lead exposure. Surveillance data for the national database are extracted from the state child tracking databases and transferred to CDC.

Since 1987, CDC has sponsored the state-based Adult Blood Lead Epidemiology and Surveillance (ABLES) program to track cases of elevated BLLs among persons ages 16 years and older, and provide intervention consultation and other assistance. The public health objective of the ABLES program, as stated in Healthy People 2010, is to reduce the number of persons with BLLs ≥25 μ/dL from work exposures to zero by 2010. The ABLES program seeks to accomplish its objective by continuing to improve its surveillance programs and helping state health and other agencies to effectively intervene to prevent further lead exposures. Intervention strategies implemented by state ABLES-reporting include: Conducting follow-up interviews with physicians, employers, and workers; investigating work sites; delivering technical assistance regarding exposure reduction or prevention; providing referrals for consultation and enforcement; and developing and disseminating educational materials and outreach programs. To coordinate their reporting and intervention activities for maximum efficiency, state ABLES programs are strongly encouraged to develop effective working relationships with the childhood lead prevention programs in their states. An estimated 2%–3% of children with BLLs ≥10 μ/dL reach those levels from exposure to lead brought home from the workplace on the clothes or in the vehicles of their adult caregivers.

ABLES is being included for the first time under this OMB approval request. ABLES is also a state laboratory-based surveillance system and many states collect both child and adult blood lead data. This request is for a 3-year extension with a change in the burden hours and inclusion of the adult blood lead surveillance system. There is no cost to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden hours
State and Local Health Departments for Child Surveillance	47	4	2	376
State and Local Health Departments for Adult Surveillance	37	4	2	296
Total				672

Dated: June 21, 2004.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–14669 Filed 6–28–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5025–N]

RIN 0938–ZA51

Medicare Program; Medicare Replacement Drug Demonstration

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the implementation of a demonstration that would pay through December 31, 2005 under Medicare Part B for drugs and biologicals that are prescribed as replacements for existing covered Medicare drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q), or both, of title XVIII of the Social Security Act. Under this demonstration certain self-injected or oral drugs that are not normally covered under Medicare Part B would be covered if they were a replacement for a non self-administered drug or biological normally provided in a physician's office. The statute requires cost sharing in the same manner as Medicare Part D. No more than 50,000 patients may be covered under the demonstration and total funding is limited to $500 million.

ADDRESSES: *Mail:* Written inquiries regarding this demonstration must be submitted by mail to the following address: Centers for Medicare & Medicaid Services, Attn: Jody Blatt, Division of Payment Policy Demonstrations, Office of Research, Development, and Information, Centers for Medicare & Medicaid Services, C4–15–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Please allow sufficient time for mailed information to be received in a timely manner in the event of delivery delays.

E-mail: Inquiries may be sent to the following e-mail address: *Section641demo@cms.hhs.gov.* Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission.

FOR FURTHER INFORMATION CONTACT: Jody Blatt, (410) 786–6921 or *Section641Demo@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 641 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) provides for a demonstration that would pay under Medicare Part B for drugs and biologicals that are prescribed as replacements for existing covered Medicare drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q), or both, of title XVIII of the Social Security Act (the Act).

For example, under this demonstration certain oral or self-injected drugs that are not normally covered under Medicare Part B would be covered if they were a replacement for a non-self-administered drug or biologic that is normally provided in a physician's office or an oral chemotherapeutic drug or biologic agent that is currently covered by Medicare under Part B. The legislation requires cost sharing in the same manner as Medicare Part D. No more than 50,000 patients may be covered under the demonstration and total funding is limited to $500 million. The demonstration is to commence with the acceptance of applications in July 2004 for coverage starting in September or October 2004. The demonstration will terminate December 31, 2005. In 2006, these drugs will be covered under Part D of Medicare for all those beneficiaries who elect to enroll in Part D.

II. Provisions of the Notice

A. Covered Drugs

In order to determine what drugs shall be covered under the demonstration, we established an inter-agency panel of clinicians to determine the criteria for defining what constitutes a ''replacement'' drug as provided in section 641 of the MMA. An initial set of criteria were shared with the public at an Open Door Forum held at CMS. Based on feedback received at this forum and subsequently in writing, the criteria have been modified. We are adopting the criteria proposed by this interagency panel as modified and have determined that, to be covered under this demonstration, a drug/biological must meet all of the following criteria:

1. A drug or biological covered under this demonstration must meet the statutory requirement of being a replacement by eliminating the concurrent need for a currently covered drug or biological for a currently covered indication.

2. Coverage of the drug or biological in the demonstration is limited to FDA approved indications and, for any drug with an existing FDA approved indication, any additional indication if such additional indication is being reviewed by the FDA; and the requester has received documentation from the FDA that no filing issues remain.

3. The drug must be at least of equal efficacy to the covered drug for which it is a replacement.

4. Use of the drug represents an advantage in terms of access and/or convenience for patients compared to the currently covered drug.

5. Drugs are not eligible for coverage under this demonstration if the drug they are replacing is not commonly provided incident to a physician service (for example, anti-hypertensives, antibiotics, oral hypoglycemics, etc.).

These criteria are consistent with the statutory requirement under section 641(a) of the MMA that the demonstration include only drugs and biologicals that are replacements for drugs currently covered under Part B. Although the statute does not explicitly require us to cover all drugs and biologicals prescribed as replacements for drugs currently covered under Part B, we nevertheless considered doing so. However, in light of the legislative directives limiting funding for the demonstration to $500 million and enrollment in the demonstration to 50,000 beneficiaries, we concluded that this demonstration's limited resources should be allocated so as to maximize the aggregate benefit to the Medicare population. We believe the criteria set forth above achieves this by focusing resources on those drugs or biologicals that have proven efficacy for the conditions indicated as well as significantly improve access to important medications for severely ill beneficiaries. Using these criteria, we have identified the following drugs/biologicals as covered under this demonstration for the following conditions:

DRUGS COVERED UNDER THE MEDICARE REPLACEMENT DRUG DEMONSTRATION

Demonstration covered indication	Drug/biological—compound name (brand name)
Rheumatoid Arthritis	Adalimumab (Humira).
	Anakinra (Kineret).
	Etanercept (Enbrel).
Multiple Sclerosis	Glatiramer acetate (Copaxone).
	Interferon beta—1a (Rebif, Avonex).
	Interferon beta—1b (Betaseron).
Osteoporosis (patient must be homebound)	Calcitonin—nasal (Miacalcin—nasal).
Pulmonary Hypertension	Bosentan (Tracleer).
Secondary Hyperparathyroidism	Doxercalciferol (Hectoral).
Paget's Disease	Alendronate (Fosamax).
	Risedronate (Actonel).
Hepatitis C	Pegylated interferon alfa-2a (Pegasys).
	Pegalated interferon alfa-2a (PEG-Intron).
CMV Retinitis	Valcyte (Valganciclovir).
Anti-Cancer	
Cutaneous T-cell Lymphoma	Bexarotene (Targretin).
Non-small cell lung cancer	Gefitinib (Iressa).
Epithelial ovarian cancer	Altretamine (Hexalen).
Chronic Myelogenous Lymphoma	Imatinib Mesylate (Gleevec).
GI Stromal Tumor	Imatinib Mesylate (Gleevec).
Anaplastic astrocytoma	Temozolomide (Temodar).
Multiple Myeloma	Thalidomide (Thalomid).
Breast Cancer	Hormonal therapy.
Stage 2–4 only	Anastrozole (Arimidex).
	Exemestane (Aromasin).

DRUGS COVERED UNDER THE MEDICARE REPLACEMENT DRUG DEMONSTRATION—Continued

Demonstration covered indication	Drug/biological—compound name (brand name)
	Letrozole (Femara). Tamoxifen (Nolvadex). Toremifene (Fareston).

We will consider covering additional drugs if they meet the criteria specified above and if the enrollment and/or funding limit for the demonstration has not been reached or is projected to be reached before the end of the demonstration.

If you believe that another drug/biological should be considered for coverage under this demonstration, please submit your request, along with all required supporting documentation, in writing as specified below.

Requests for consideration must explicitly list the drug/biological to be covered (trade and generic names), manufacturer, FDA approved indication(s), intended disease(s) and/or patient populations for the demonstration project (including a reference to the applicable treatment guideline, for example, the National Comprehensive Cancer Network (NCCN) guideline), typical dosing pattern in each relevant patient population, the Part B covered drug/biological that will be replaced, and how it meets each of the criteria noted above. Additionally, you must submit information describing the projected average annual cost of the medication following typical dosing patterns and any savings that Medicare might realize as a result of using this drug/ biological as a replacement. Those requesting inclusion of a drug or biological that has not yet received FDA approval for the proposed indication but otherwise meets all of the criteria must submit a letter from the FDA verifying that the FDA has received all of the data it needs to complete its review and that no further filing issues remain.

B. Implementation

We have entered into a contract with TrailBlazer Health Enterprises, L.L.C. (TrailBlazer) to handle eligibility determination, enrollment and claims processing for this demonstration. Under this arrangement, TrailBlazer will subcontract with Advance PCS, a Caremark Company (Caremark), to provide pharmacy benefit management (PBM) services.

Starting July 6, 2004, TrailBlazer will begin accepting applications to participate in this demonstration. Applications may be downloaded from our Web site: *http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp* or obtained by calling 1–866–563–5386 any time after 8 a.m. Eastern time on July 6, 2004. Calls prior to that time will not be accepted. Applications must be received by 5 p.m. Eastern time September 30, 2004. Applications received by August 16, 2004 will be eligible for an early selection process for coverage under the demonstration effective September 1, 2004.

Applications will be considered under two categories: (1) Those seeking coverage for a covered cancer drug and (2) those seeking coverage for any other replacement drug covered under the demonstration. The purpose of creating two enrollment categories is to insure that at least 40 percent of the available funding goes toward oral cancer treatments as specified in the Medicare Modernization Act of 2003 ''Conference Agreement.'' If more persons submit applications than we believe we can accommodate because of the limits for either or both of the enrollment categories specified, participants will be chosen on a random basis among all completed applications received. Notification to applicants of their status regarding participation in the demonstration will be sent out by October 13, 2004. For those participating in the demonstration, coverage will be effective October 18, 2004.

If fewer applications are received than the maximum number of enrollees permitted or than can be covered within the projected funding limits, then all eligible beneficiaries who have submitted applications by the deadline will be enrolled in the demonstration with an effective date of October 18, 2004. To the extent that enrollment slots remain unfilled and we project available funding for additional participants, additional applications will be considered on a rolling basis after that date, although we do not anticipate this will occur.

Those selected to participate will receive a ''welcome packet'' from Caremark including information on how to fill their prescriptions as well as supplemental information about their demonstration pharmacy benefit.

C. Eligibility

In order to be eligible for participation in this demonstration, a beneficiary must meet the following criteria:

- The beneficiary must have Part A and Part B.
- Medicare must be the beneficiary's primary health insurance.
- The beneficiary must reside in one of the 50 states or the District of Columbia.

Beneficiaries who are members of Medicare Advantage or other Medicare coordinated care health plans as well as those covered under the traditional Medicare Fee-For-Service program are eligible to enroll.

Because a primary purpose of this demonstration is to increase access to important medications in advance of the full implementation of the Medicare Part D drug benefit in 2006, those beneficiaries who already have a comprehensive drug coverage plan will not be eligible to enroll. This includes beneficiaries who are covered under Tricare, the PACE program under section 1894 of the Act, and most Medicaid and SCHIP plans, as well as those who are covered under a comprehensive Medicare Advantage plan or an employer or union sponsored retiree plan. However, beneficiaries without any drug coverage and beneficiaries with more limited drug coverage, such as that offered by Medicare supplemental (employer-sponsored prescription drug coverage (or other alternative coverage)) plans and some Medicare Advantage or other Medicare coordinated care health plans, are eligible to apply for participation. Beneficiaries who are eligible for VA benefits are also eligible to apply for this demonstration if they do not use their VA benefits to pay for medications. Beneficiaries with questions about eligibility may contact 1–866–563–5386. Beneficiaries who have a Medicare sponsored discount drug card may participate in the demonstration, but they may not use the card to pay for drugs or biologicals covered under the demonstration. A separate demonstration specific card will be issued to beneficiaries participating in this demonstration.

In order to apply for this demonstration, a beneficiary must

obtain certification from their physician stating that the beneficiary (1) has a medical condition for which coverage of the demonstration drug is allowed under the demonstration and (2) either the physician has already written a prescription for the demonstration drug for the beneficiary or intends to do so if the beneficiary is enrolled in the demonstration. The beneficiary does not need to be taking either the demonstration drug or a specific Medicare Part B covered drug in order to be eligible for this demonstration. Beneficiaries who are newly diagnosed and/or for whom the covered drug is prescribed for the first time during the course of the demonstration may apply at that time and will be considered for participation in the demonstration to the extent new applications can be considered.

Beneficiaries who participate in the demonstration will retain all of their Medicare benefits and should follow their physician's guidance regarding any changes in medication and/or treatment that may be medically appropriate.

D. Beneficiary Cost Sharing

In accordance with the requirements of section 641 of the MMA, cost sharing under this demonstration must be applied in the same manner as the standard prescription drug benefit under Part D that will be effective in 2006, as described in section 1860D–2(b) of the Social Security Act (the ''Act''). However, because this demonstration will not begin covering benefits until September, beneficiary out-of-pocket cost sharing for 2004 will be pro-rated to approximately one-third of the standard amount to reflect the reduced benefit year. In 2005, the full standard cost-sharing amount will be applied.

Therefore, while beneficiaries will not be required to pay a premium for participating in the demonstration, they will be required to meet an annual deductible before benefits are paid. This deductible will be applied each calendar year a beneficiary is covered, regardless of when the beneficiary enrolls in the demonstration.

In 2005, a standard annual deductible of $250 will be applied. After the annual deductible has been reached, the beneficiary must pay 25 percent coinsurance for the cost of each prescription until the beneficiary has received covered replacement drugs totaling $2,250, which includes amounts paid out of pocket by the beneficiary (the $250 deductible plus $500 worth of ''25% coinsurance'' for a total of $750) and amounts paid by Medicare under this demonstration. Once the beneficiary has received $2,250 in replacement drugs, the beneficiary will be responsible for paying 100 percent of all costs of the covered replacement drug until the beneficiary has paid an additional $2,850 for a total of $3,600 out-of-pocket. Covered replacement drug costs paid by an individual (such as a family member) or a state pharmacy assistance plan on the beneficiary's behalf, and low-income assistance paid by Medicare under the demonstration on behalf of beneficiaries eligible for such assistance (see II E. below), count toward the beneficiary's $3,600 ''out-of-pocket limit''. Under the demonstration, in some cases, funds provided by charitable organizations may also count toward the beneficiary's out-of-pocket limit. However, costs for which the beneficiary is reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement do not count toward the $3,600 out-of-pocket limit. Once the $3,600 ''out-of-pocket limit'' has been reached, the beneficiary will pay the greater of 5 percent of the cost of the covered replacement drug or a fixed co-payment of $2 for generic or preferred brand drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i)) or $5 for all other drugs.

As noted above, due to fact that the demonstration is not starting in 2004 until approximately two-thirds of the calendar year has passed, out-of-pocket costs for beneficiaries who enroll in 2004 will be reduced by approximately two-thirds. The annual deductible will be reduced from $250 to $85. This deductible will be applied regardless of when in 2004 a beneficiary enrolls. Once the beneficiary has met the deductible, s/he will pay 25% of the next $660 in allowable costs until s/he has paid an additional $165 out-of-pocket. The beneficiary will then be responsible for paying 100 percent of the allowed cost of the covered replacement drug until the beneficiary has paid an additional $950 for a total of $1,200 out-of-pocket ($85 deductible plus $165 at the 25% coinsurance level plus $950 at the 100% coinsurance level). The table below summarizes the out-of-pocket costs under the demonstration for 2004 and 2005.

	2004 (Sept–Dec)	2005 (Jan–Dec)
Deductible		
Standard Benefit *	• $85	• $250
25% Coinsurance Range		
• Allowable Cost of Drugs	• 660	• 2,000
• 25% Out of Pocket	• 165	• 500
100% Coinsurance ''Donut''		
• 100% Out-of-Pocket Payments (in addition to above)	• 950	• 2,850
Catastrophic Limit		
1. Total Allowable Cost of Drugs	• 1,695 **	• 5,100 **
2. Total Out of Pocket Payments	• 1,200	• 3,600

* Some low-income beneficiaries, those with incomes between 135% and 150% of the Federal Poverty Level, will also have the deductible reduced from $50 to $20 in 2004. Other low-income beneficiaries will not pay any deductible in either year.

** Because beneficiary cost-sharing under the demonstration that is paid for by a group health plan, insurer or otherwise, or similar third party payment arrangement will not count toward the annual out-of-pocket limit, the total drug spending amount that triggers catastrophic coverage may be higher for beneficiaries with these alternative sources of coverage.

Beneficiaries may receive their drugs on a retail or mail order basis, but must get them through Caremark, the pharmacy benefit manager contracting with TrailBlazer to implement this demonstration. Caremark has a national network of pharmacies. More specific information about the network and pharmacies available can be obtained by calling 1–866–563–5386. Upon enrolling in the demonstration, beneficiaries will be mailed a complete package of information, including a demonstration identification card and instructions on how to fill their prescriptions for the demonstration-covered drug. This card may be used

only for drugs covered under the demonstration.

E. Low-Income Assistance

Beneficiaries who meet the criteria specified in Part D, section 1860D–14 of the Act, for low-income assistance will be eligible for assistance under this demonstration. Tables 1A and 1B specify the different cost sharing requirements for the standard benefit level as well as the different low-income options for 2004 and 2005. Table 2 identifies which benefit levels apply based on a person's annual income and available financial resources.

Beneficiaries, or their authorized representatives, will be required to submit an application form attesting to the beneficiary's annual income and financial resources in order to be considered for the subsidy.

F. Application Instructions

Starting on or before July 6, 2004, application forms will be available from our Web site: *http://www.cms.hhs.gov/researchers/demos/drugcoveragedemo.asp.* Alternatively, individuals may call 1–866–563–5386 (TTY: 1–866–5387) any time after 8 a.m. Eastern time on July 6, 2004 to have an application mailed to them. Calls prior to that time will not be accepted.

Applications must be received by TrailBlazer by 5 p.m. eastern time, September 30, 2004. Applications should be sent to the following address: Medicare Replacement Drug Demonstration, c/o TrailBlazer Health Enterprises, L.L.C., P.O. Box 5136, Timonium, MD 21094.

The application form consists of two parts. Both parts must be filled in completely and submitted by September 30, 2004 in order to be considered for the demonstration.

The first part of the form requests basic demographic information, information on the drug being requested and the availability of alternative insurance coverage for prescription drugs. Because this demonstration is intended to increase access to prescription drugs, beneficiaries who have comprehensive, alternative drug coverage through Medicaid, SCHIP, the PACE program under section 1894 of the Act, Tricare, retiree insurance, or other source are not eligible to enroll. However, beneficiaries who have more limited drug coverage such as under a Medicare supplement (employer-sponsored prescription drug coverage (or other alternative coverage, including Medigap plans)) plan are eligible to enroll. Beneficiaries who are enrolled in a Medicare Advantage or other Medicare coordinated care health plan are also eligible to enroll if they do not have comprehensive drug coverage under that plan that would cover the replacement drug.

The second part of the application form is a certification from the physician who is prescribing the replacement drug for the beneficiary. The physician must submit this signed statement specifying that he (or she) is prescribing or will be prescribing the medication for the covered condition.

Beneficiaries who believe they qualify for low-income assistance (see II.E above) must also complete and sign an attestation of income and resources. The rules for low-income assistance, including coverage levels and determination of eligibility, have been established to be consistent with what will be in effect in 2006 when the Medicare Part D drug benefit is implemented. Information submitted on the application for low-income assistance is subject to formal verification by CMS. Enrollment in the demonstration will be determined on a ''need-blind'' basis, that is, without regard to whether a beneficiary has also submitted an application for the low-income subsidy. Moreover, applications for the low-income subsidy may be submitted at any time during the duration of the demonstration and will be considered as long as funds are available. However, the low-income subsidy will not be provided retroactively.

G. Submission of Written Materials

Those wishing to propose additional drugs/biologicals to be considered for coverage under the demonstration must submit written information documenting how the proposed drug meets the criteria specified in section II(A) of this notice. While the format for this information is not prescribed, we are requesting that all of the criteria listed above be fully addressed in the materials submitted.

Written materials may be submitted by mail or e-mail to the addresses listed above under ''Inquiries, Registration and Submission of Information.''

BILLING CODE 4120–01–P

TABLE 1A – MEDICARE REPLACEMENT DRUG DEMONSTRATON – OUT-OF-POCKET COSTS FOR CY 2004

Benefit Categories →	Benefit Level 1 (Standard)	Benefit Level 2	Benefit Level 3	Benefit Level 4	Benefit Level 5
Deductible	$85	$20	$0	$0	$0
After the annual deductible, you pay this amount for each prescription until you have paid a total of $1,200 out of pocket[1]:	▪ 25% coinsurance until you have paid $165 in additional out of pocket costs and then, ▪ 100% of all costs until your total out of pocket costs = $1,200(that is, the next $950 in allowable costs out-of-pocket)	▪ 15% coinsurance	▪ A fixed co-payment of $2 for generic or preferred multi-brand drugs or $5 for all other drugs	▪ A fixed co-payment of $1 for generic or preferred multi-brand drugs or $3 for all other drugs	You pay nothing
Once you have paid $1,200 in total out of pocket costs, you pay this amount for each prescription:	The greater of: ▪ 5% or ▪ A fixed co-payment of $2 for generic or preferred multi-brand drugs or $5 for all other drugs	You pay: ▪ A fixed co-payment of $2 for generic or preferred multi-brand drugs or $5 for all other drugs	You pay nothing	You pay nothing	You pay nothing

[1]Any amount paid by other insurance, with the exception of a State pharmacy assistance program or certain charitable organizations may NOT be counted toward you out-of-pocket limit.

TABLE 1B – MEDICARE REPLACEMENT DRUG DEMONSTRATON – OUT-OF-POCKET COSTS FOR CY 2005

Benefit Categories →	Benefit Level 1 (Standard)	Benefit Level 2	Benefit Level 3	Benefit Level 4	Benefit Level 5
Deductible	$250	$50	$0	$0	$0
After the annual deductible, you pay this amount for each prescription until you have paid a total of $3,600 out of pocket[1]:	▪ 25% coinsurance until you have paid $500 in additional out of pocket costs and then, ▪ 100% of all costs until your total out of pocket costs = $3,600 (that is, the next $1,350 in allowable costs out of pocket)	▪ 15% coinsurance	▪ A fixed co-payment of $2 for generic or preferred multi-brand drugs or $5 for all other drugs	▪ A fixed co-payment of $1 for generic or preferred multi-brand drugs or $3 for all other drugs	You pay nothing
Once you have paid $3600 in total out of pocket costs, you pay this amount for each prescription:	The greater of: ▪ 5% or ▪ A fixed co-payment of $2 for generic or preferred multi-brand drugs or $5 for all other drugs	You pay: ▪ A fixed co-payment of $2 for generic or preferred multi-brand drugs or $5 for all other drugs	You pay nothing	You pay nothing	You pay nothing

[1]Any amount paid by other insurance, with the exception of a State pharmacy assistance program or certain charitable organizations, may NOT be counted toward you out-of-pocket limit.

TABLE 2 – BENEFIT CATEGORIES APPLICABLE BASED ON ANNUAL INCOME AND FINANCIAL ASSETS

If your Income Is: / And Your Total Assets are →	Less than: ▪ $6000 for an individual, or ▪ $9000 for a couple	Between ▪ $6000 and $10,000 for an individual, or ▪ $9000 and $20,000 for a couple	Over ▪ $10,000 for an individual, or ▪ $20,000 for a couple
Less than 100% of the Federal Poverty Level (FPL) AND you are a full benefit dual Medicare and Medicaid eligible beneficiary (1)(2)	Benefit Level 4	Benefit Level 4	Benefit Level 4
100% or more than the Federal Poverty Level (FPL) AND you are a full benefit dual Medicare and Medicaid eligible beneficiary (1)(2)	Benefit Level 3	Benefit Level 3	Benefit Level 3
Less than 135% of the FPL and you are not a full benefit dual Medicare and Medicaid eligible beneficiary	Benefit Level 3	Benefit Level 2	Benefit Level 1
135% or more of the FPL but less than 150% of the FPL and you are not a full benefit dual Medicare and	Benefit Level 2	Benefit Level 2	Benefit Level 1
150% or more of the FPL and you are not a full benefit dual Medicare and	Benefit Level 1	Benefit Level 1	Benefit Level 1

NOTES: (1) Institutionalized full benefit dual Medicare and Medicaid eligible beneficiaries will be covered under **Benefit Level 5** (See Tables 1A and 1B).

(2) Most full benefit dual Medicare and Medicaid eligible beneficiaries receive a comprehensive drug benefit through the Medicaid program. Only beneficiaries who do not already have a comprehensive drug benefit through their Medicaid program are eligible to participate in this demonstration.

TABLE 3 – FEDERAL POVERTY LEVEL GUIDELINES FOR 2004

	100 % of Federal Poverty Level		135% of Federal Poverty Level		150% of Federal Poverty Level	
	Individual	**Couple**	**Individual**	**Couple**	**Individual**	**Couple**
Lower 48 States	$9,310	$12,490	$12,569	$16,862	$13,965	$18,735
Alaska	$11,630	$15,610	$15,701	$21,074	$17,445	$23,415
Hawaii	$10,700	$14,360	$14,445	$19,386	$16,050	$21,540

BILLING CODE 4120–01–C

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection must be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Due to the following reasons, CMS requested that OMB grant OMB emergency approval of the collection requirements associated with this demonstration Section 641 of the MMA: (1) The statute required that this demonstration begin 90 days after passage of the legislation, which was March 8, 2004; (2) due to the complexities of implementing this demonstration, CMS was unable to meet that deadline; and (3) because of the importance of this demonstration to beneficiaries with serious illnesses and the already delayed time frame, it was urgent that there not be further delays.

Based on the justification referenced above for emergency approval, with OMB concurrence, on May 19, 2004 Volume 69, Number 97, Pages 28894–28895, CMS announced the initiation of procedural requirements set forth in 5 CFR 1320.13 to facilitate compliance with Chapter 25 of Title 44 of United States Code. As the result, the collection requirements associated with this demonstration, ''Application for Participation in Medicare Replacement Drug Demonstration'', were approved under OMB control number 0938–0924.

It should be noted that during the 180-day emergency approval period, CMS will publish a **Federal Register** notice announcing the initiation of an extensive 60-day public comment period on these requirements. Upon completion of the 60-day comment period, we will submit the requirements for OMB review and an extension of this emergency approval.

Authority: Section 641 of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

(Catalog of Federal Domestic Assistance Program No. 93.778 and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 4, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–14673 Filed 6–24–04; 3:00 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 1976N–0080 and 2000N–1610]

Prescription Drug Products; Digoxin Elixir; Extension to Obtain Marketing Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it will continue to exercise enforcement discretion to assure the continued availability of digoxin elixirs after June 28, 2004, allowing manufacturers to continue to market these products without approved applications until December 28, 2004. FDA is granting this extension to give manufacturers of digoxin elixir additional time to obtain marketing approval and bring products to market.

DATES: The date by which manufacturers must obtain marketing approval is extended to December 28, 2004.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 2002 (67 FR 42992), FDA published a final rule revoking § 310.500 (21 CFR 310.500), which established conditions for marketing digoxin products for oral use (tablets and elixir). The agency concluded that § 310.500 was no longer necessary because the products, which are new drugs, can be regulated under the approval process for new drug applications and abbreviated new drug applications as set forth in the Federal Food, Drug, and Cosmetic Act (the act). Previously, in the **Federal Register** of November 24, 2000 (65 FR 70573), we reaffirmed the new drug status of oral digoxin products and announced that these products required approved applications for marketing.

The June 26, 2002, final rule advised that manufacturers who were marketing digoxin elixir drug products on or before June 26, 2002, may continue to market their products until June 28, 2004.[1] The final rule stated that a manufacturer who marketed a digoxin elixir drug product without an approved application after that date would be subject to regulatory action.

We permitted this period of continued marketing because we regard digoxin elixir products as medically necessary and, therefore, wanted to allow sufficient time for manufacturers to conduct the required studies and to prepare and submit applications, as well as to allow the agency sufficient time to review these applications. It now appears that as of June 28, 2004, there may not be any manufacturers prepared to market digoxin elixir under an approved application. To assure the continued availability of digoxin elixirs after June 28, 2004, we have decided to extend for 6 months, until December 28, 2004, the date by which manufacturers must obtain marketing approval. This extension will only apply to manufacturers who have submitted applications to FDA and who continue to pursue approval of their applications with due diligence. We will reexamine the need for a continued exercise of enforcement discretion at the end of this 6-month period. In making this determination, we will consider whether there is an approved digoxin elixir product on the market and whether the manufacturer is capable of producing sufficient product to meet patient needs.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352, 355)) and under authority delegated to the Associate Commissioner for Policy and Planning (21 CFR 5.20).

Dated: June 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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[1] After June 26, 2002, a new digoxin elixir drug product could not be introduced into the market unless we had approved an application for that product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) Sec. 110.310 entitled ''Prior Notice of Imported Food