

Dated: December 27, 2006.

Michelle Shortt,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory
Affairs.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-301]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Certification of Medicaid Eligibility Control (MEQC) Payment Error Rates and Supporting Regulations at 42 CFR 431.800-431.865; *Use:* Medicaid Eligibility Quality Control (MEQC) is operated by Title XIX agencies to monitor and improve the administration of its Medicaid program. The traditional MEQC program is based on State reviews of Medicaid beneficiaries identified through a statistically reliable statewide sample of cases selected from the eligibility files. These reviews are conducted to determine whether the sampled cases meet applicable Title XIX eligibility requirements. State agencies are required to submit the Payment Error Rate form to their respective CMS Regional Office. Regional Office staff

will review these forms for completeness and will forward these forms to central office for compilation of error rate charts for projected quarterly withholdings and/or fiscal disallowances. *Form Number:* CMS-301 (OMB#: 0938-0246); *Frequency:* Recordkeeping and Reporting—Semi-annually; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 102; *Total Annual Hours:* 22,515.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395-6974.

Dated: December 27, 2006.

Michelle Shortt,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory
Affairs.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1488-CN2]

RIN 0938-A012

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Final Fiscal Year 2007 Wage Indices and Payment Rates After Application of Revised Occupational Mix Adjustment to the Wage Index; Corrections

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

ACTION: Correction of notice.

SUMMARY: This document corrects wage index and technical errors that appeared in the notice published in the **Federal**

Register on October 11, 2006 entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.

DATES: Effective Date: Corrections listed in items 10 through 12 of section III. of this notice are effective as of October 1, 2006. The corrections to the wage index listed in items 2a, 3 through 8a, and 9a of section III. of this notice are effective as of November 3, 2006. The corrections to the wage index listed in items 1, 2b, 8b, and 9b of section III. of this notice are effective as of November 21, 2006.

FOR FURTHER INFORMATION CONTACT: Marc Hartstein, (410) 786-4548.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 06-8471 of October 11, 2006 (71 FR 59886), the notice entitled "Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates: Final Fiscal Year 2007 Wage Indices and Payment Rates After Application of Revised Occupational Mix Adjustment to Wage Index" (hereinafter referred to as the "FY 2007 IPPS notice"), there were a number of technical errors that are identified and corrected in the Correction of Errors section (items 10 through 12 of section III. of this notice). These technical corrections are effective October 1, 2006.

In addition, in October 2006, we became aware of an error in the calculation of the FY 2007 wage index for a number of rural areas and several hospitals that are reclassified to those areas. The error also affected some hospitals in urban areas that are assigned the statewide rural wage index floor. Section 412.64(k)(1) of the regulations requires that wage index corrections made after October 1 are effective prospectively for the remainder of the fiscal year from the date the fiscal intermediaries are informed of the correction. We recalculated the wage indices for the affected hospitals, and on November 3, 2006, sent a Joint Signature Memorandum to the fiscal intermediaries informing them to pay hospitals using the corrected wage indices. Subsequent to the November 3, 2006 Joint Signature Memorandum, additional errors in the wage indices were brought to our attention and were corrected through a November 21, 2006 Joint Signature Memorandum. Therefore, the corrected FY 2007 wage indices are effective beginning November 3, 2006 or November 21, 2006. Accordingly, the wage index provisions of this correction notice are corrections to the tabulation of the rates paid to hospitals. We note that the

corrections to the impact analysis (item 1 of section III. of this notice) are effective as of November 3, 2006 since the additional corrections made based on the November 21, 2006 Joint Signature Memorandum had no significant effect on the impact analysis.

II. Summary of the Corrections to the FY 2007 IPPS Notice

We made corrections to wage index values and geographic adjustment factors (GAFs) that were published in Tables 2, 4A-1, 4A-2, 4B-1, 4B-2, 4C-1, and 4C-2. In addition, we are making technical corrections to— (1) the out-migration adjustments and qualifying counties that were published in Table 4J; and (2) the list of diagnosis-related groups (DRGs), relative weighting factors, and geometric and arithmetic mean length of stay (LOS) that were published in Table 5.

III. Correction of Errors

In FR Doc. 06-8471 of October 11, 2006 (71 FR 59886), make the following corrections:

1. On pages 59893 and 59894, in Table I.—Impact Analysis of Changes for FY 2007, the figures in the last column (All FY 2007 changes^a) are corrected to read as follows:

IMPACT ANALYSIS OF FINAL CHANGES FOR FY 2007 OPERATING PROSPECTIVE PAYMENT SYSTEM
[Percent changes in payments per case]

	All FY 2007 changes (4)
All Hospitals	3.5
By Geographic Location:	
Urban hospitals	3.5
Large urban areas (populations over 1 million)	3.5
Other urban areas (populations of 1 million or fewer)	3.4
Rural hospitals	4
Bed Size (Urban):	
0-99 beds	3.5
100-199 beds	3.8
200-299 beds	3.6
300-499 beds	3.4
500 or more beds	3.2
Bed Size (Rural):	
0-49 beds	4.7
50-99 beds	4.9
100-149 beds	3.7
150-199 beds	3.3
200 or more beds	3.0
Urban by Region:	
New England	3.9
Middle Atlantic	3.9
South Atlantic	3.2
East North Central	3.4
East South Central	2.7
West North Central	2.8
West South Central	3.4

IMPACT ANALYSIS OF FINAL CHANGES FOR FY 2007 OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued
[Percent changes in payments per case]

	All FY 2007 changes (4)
Mountain	3.7
Pacific	3.7
Puerto Rico	2.0
Rural by Region:	
New England	6.3
Middle Atlantic	5.2
South Atlantic	3.9
East North Central	3.8
East South Central	3.5
West North Central	4.3
West South Central	4.1
Mountain	2.7
Pacific	3.3
By Payment Classification:	
Urban hospitals	3.4
Large urban areas (populations over 1 million)	3.5
Other urban areas (populations of 1 million or fewer)	3.4
Rural areas	4.0
Teaching Status:	
Non-teaching	3.8
Fewer than 100 Residents	3.4
100 or more Residents	3.2
Urban DSH:	
Non-DSH	3.6
100 or more beds	3.4
Less than 100 beds	3.6
Rural DSH:	
SCH	4.6
RRC	3.5
Other Rural:	
100 or more beds	3.5
Less than 100 beds	3.9
Urban teaching and DSH:	
Both teaching and DSH	3.3
Teaching and no DSH	3.3
No teaching and DSH	3.7
No teaching and no DSH ..	3.6
Rural Hospital Types:	
RRC	3.5
SCH	3.6
MDH	9.0
SCH and RRC	3.1
MDH and RRC	14.1
Unknown.	
Type of Ownership:	
Voluntary	3.5
Proprietary	3.5
Government	3.4
Unknown	7.6
Medicare Utilization as a Percent of Inpatient Days:	
0-25	3.6
25-50	3.3
50-65	3.7
Over 65	3.8
Unknown	4.4
Hospitals Reclassified by the Medicare Geographic Classification Review Board:	
FY 2005 Reclassifications.	

IMPACT ANALYSIS OF FINAL CHANGES FOR FY 2007 OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued
[Percent changes in payments per case]

	All FY 2007 changes (4)
Urban Hospitals Reclassified by the Medicare Geographic Classification Review Board: First Half FY 2007 Reclassifications	3.7
Urban Nonreclassified, First Half FY 2007	3.4
All Urban Hospitals Reclassified Second Half FY 2007	3.5
Urban Nonreclassified Hospitals Second Half FY 2007	3.4
All Rural Hospitals Reclassified Second Half FY 2007	3.6
Rural Nonreclassified Hospitals Second Half FY 2007	4.5
All Section 401 Reclassified Hospitals	5.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	4.5
Section 508 Hospitals	2
Specialty Hospitals	—
Cardiac Specialty Hospitals	1.2

2. On pages 59903 through to 59968, in Table 2.—Hospital Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2005; Hospital Wage Indexes for Federal Fiscal Year 2007; Hospital Average Hourly Wages for Federal Fiscal Years 2005 (2001 Wage Data), 2006 (2002 Wage Data), and 2007 (2003 Wage Data); Wage Indexes and 3-Year Average of Hospital Average Hourly Wages, for the listed providers, the wage indexes are corrected to read as follows:
a. Effective November 3, 2006

Provider No.	FY 2007 wage index
040039	0.8341
040047	0.8431
070002	1.2452
070003	1.2461
070004	1.2452
070007	1.2452
070008	1.2452
070009	1.2452
070011	1.2452
070012	1.2452
070015	1.2452
070020	1.2525
070021	1.2461
070024	1.2452
070025	1.2452
070027	1.2452
070029	1.2452
070035	1.2452

Provider No.	FY 2007 wage index	Provider No.	FY 2007 wage index	Provider No.	FY 2007 wage index
070038	1.2452	260163	0.8341	230029	1.0381
100025	0.8847	260195	0.8341	230047	1.0381
100026	0.8847	280061	0.9048	230071	1.0381
100027	0.8847	340073	0.9828	230130	1.0381
100048	0.8847	380002	1.0282	230151	1.0381
100054	0.8847	380040	1.0152	230195	1.0381
100062	0.8907	380052	1.0152	230204	1.0381
100081	0.8847	380081	1.0152	230207	1.0381
100093	0.8847	390044	1.1196	230207	1.0381
100102	0.8972	390096	1.1196	230223	1.0381
100106	0.8847	430094	0.9048	230227	1.0381
100108	0.8847	470001	1.0770	230254	1.0381
100118	0.9245	470005	1.0383	230257	1.0381
100122	0.8847	470012	1.0383	230264	1.0381
100124	0.8847	470024	1.0383	230269	1.0381
100134	0.8847	500002	1.0390	230277	1.0381
100142	0.8847	500007	1.0598	390065	1.0977
100156	0.8972	500012	1.0390	390138	1.0977
100160	0.8847	500019	1.0603	490005	1.0977
100175	0.9078	500031	1.0390		
100212	0.8907	500033	1.0390		
100223	0.8847	500036	1.0390		
100231	0.8847	500037	1.0390		
100242	0.8847	500049	1.0390		
100266	0.8847	500053	1.0390		
100290	0.9429	500058	1.0390		
100292	0.8847	500148	1.0390		
230254	1.0381	530002	0.9128		
230257	1.0381	530006	0.9128		
230264	1.0381	530008	0.9128		
230269	1.0381	530009	0.9128		
230277	1.0381	530010	0.9128		
260004	0.8341	530011	0.9128		
260006	0.8341	530014	0.9128		
260015	0.8345	530017	0.9128		
260022	0.8615	530032	0.9128		
260024	0.8341	530008	0.9057		
260047	0.8348	530009	0.9057		
260059	0.8341	530010	0.9057		
260061	0.8341	530011	0.9057		
260070	0.8341	530014	0.9057		
260074	0.8499	530017	0.9057		
260078	0.8341	530032	0.9057		
260080	0.8341				
260097	0.8766				
260113	0.8341				
260116	0.8341				
260119	0.8345				
260142	0.8341				
260147	0.8341	230013	1.0381		
260160	0.8341	230019	1.0381		

3. On page 59968 in Table 2.—Hospital Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2005; Hospital Wage Indexes for Federal Fiscal Year 2007; Hospital Average Hourly Wages for Federal Fiscal Years 2005 (2001 Wage Data), 2006 (2002 Wage Data), and 2007 (2003 Wage Data); Wage Indexes and 3-Year Average of Hospital Average Hourly Wages, the table is corrected by adding a note to the end of the table to read as follows:

Note: Due to the expiration of section 508 of the MMA, the wage index values for some hospitals will change in the second half of the fiscal year. The wage index values in this table reflect an average of the first half of FY 2007 (October 1, 2006–March 31, 2007) and second half of FY 2007 (April 1–September 30, 2007).

b. Effective November 21, 2006.

4. On pages 59975 through to 59998, in Table 4A–1.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Urban Areas by CBSA, for the listed CBSAs, the wage indexes and GAFs are corrected to read as follows:

CBSA code	Urban area (constituent counties)	Wage index	GAF
15540	Burlington-South Burlington, VT Chittenden County, VT ² Franklin County, VT Grand Isle County, VT	1.0383	1.0261
23020	Fort Walton Beach-Crestview-Destin, FL ² Okaloosa County, FL	0.8847	0.9195
25540	Hartford-West Hartford-East Hartford, CT ^{1 2} Hartford County, CT Litchfield County, CT Middlesex County, CT Tolland County, CT	1.2452	1.1620
28420	Kennewick-Richland-Pasco, WA ² Benton County, WA Franklin County, WA	1.0390	1.0265
30300	Lewiston, ID-WA (WA Hospitals) ² Nez Perce County, ID Asotin County, WA	1.0390	1.0265

CBSA code	Urban area (constituent counties)	Wage index	GAF
31020	Longview, WA Cowlitz County, WA	1.0390	1.0265
34580	Mount Vernon-Anacortes, WA Skagit County, WA	1.0390	1.0265
35300	New Haven-Milford, CT ³ New Haven County, CT	1.2452	1.1620
35980	Norwich-New London, CT New London County, CT	1.2452	1.1620
36100	Ocala, FL ² Marion County, FL	0.8847	0.9195
37460	Panama City-Lynn Haven, FL Bay County, FL	0.8847	0.9195
37860	Pensacola-Ferry Pass-Brent, FL Escambia County, FL Santa Rosa County, FL	0.8847	0.9195
48300	Wenatchee, WA Chelan County, WA Douglas County, WA	1.0390	1.0265
49420	Yakima, WA Yakima County, WA	1.0390	1.0265

¹ Large urban area.

² Hospitals geographically located in the area are assigned the statewide rural wage index for FY 2007.

³ For this area, the wage index and GAF on this table are only effective from October 1, 2006 through March 31, 2007. See Table 4A-2 for the values that are effective from April 1 through September 30, 2007.

5. On page 59998, in Table 4A-2.— Urban Areas by CBSA for the Period the listed CBSAs, the wage indexes and Wage Index and Capital Geographic Adjustment Factor (GAF) for Certain April 1 Through September 30, 2007, for GAFs are corrected to read as follows:

CBSA code	Urban area (constituent counties)	Wage index	GAF
16940	Cheyenne, WY	0.9057	0.9344
35300	New Haven-Milford, CT	1.2452	1.1620

6. On pages 59998 and 59999, in Table 4B-1.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Rural Areas by CBSA—FY 2007, for the listed CBSAs, the wage indexes and GAFs are corrected to read as follows:

CBSA code	Nonurban area	Wage index	GAF
07	Connecticut	1.2452	1.1620
10	Florida	0.8847	0.9195
26	Missouri	0.8341	0.8832
38	Oregon ²	1.0152	1.0104
47	Vermont	1.0383	1.0261
50	Washington	1.0390	1.0265

7. On page 59999, in Table 4B-2.— Rural Areas by CBSA for the Period the listed CBSA, the wage index and Wage Index and Capital Geographic Adjustment Factor (GAF) for Certain April 1 Through September 30, 2007, for GAF is corrected to read as follows:

CBSA code	Nonurban area	Wage index	GAF
53	Wyoming	0.9057	0.9344

8. On pages 59999 through to 60003, in Table 4C-1.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Hospitals That Are Reclassified by CBSA, for the listed CBSAs, the wage indexes and GAFs are corrected to read as follows:

a. Effective November 3, 2006.

CBSA code	Area	Wage index	GAF
23020	Fort Walton Beach-Crestview-Destin, FL	0.8847	0.9195
25540	Hartford-West Hartford-East Hartford, CT (CT Hospitals)	1.2452	1.1620
27860	Jonesboro, AR (MO Hospitals)	0.8345	0.8835
28420	Kennewick-Richland-Pasco, WA	1.0390	1.0265
38340	Pittsfield, MA	1.0383	1.0261

CBSA code	Area	Wage index	GAF
07	Connecticut	1.2452	1.1620
10	Florida (FL Hospitals)	0.8847	0.9195
14	Illinois (MO Hospitals)	0.8341	0.8832
16	Iowa	0.8615	0.9029
26	Missouri	0.8341	0.8832
30	New Hampshire	1.0770	1.0521
38	Oregon	1.0152	1.0104
50	Washington (WA Hospitals)	1.0390	1.0265
53	Wyoming	0.9048	0.9338

b. Effective November 21, 2006.

CBSA code	Area	Wage index	GAF
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	1.0977	1.0659

9. On page 60003, in Table 4C-2.—Wage Index and Capital Geographic Adjustment Factor (GAF) for Certain Hospitals That Are Reclassified by

CBSA for the Period April 1 Through September 30, 2007*, CBSAs 35300 and 19804 are corrected and CBSA 47894 is

added. The wage indexes and GAFs are corrected to read as follows:

a. Effective November 3, 2006.

CBSA code	Area	Wage index	GAF
19804	Detroit-Livonia-Dearborn, MI	1.0381	1.0192
35300	New Haven-Milford, CT	1.2452	1.1620

b. Effective November 21, 2006.

CBSA code	Area	Wage index	GAF
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	1.0977	1.0659

10. On pages 60004 through to 60012, in Table 4J.—Out-Migration Adjustment—FY 2007, provider number

010009 is corrected and provider number 010010 is added to read as follows:

a. Effective October 1, 2006.

Provider No.	Reclassified between 10/1/06 and 3/31/07	Reclassified between 4/1/07 and 9/30/07	Out-migration adjustment	Qualifying county name
010009	*	*	0.0092	MORGAN.
010010	*	*	0.0259	MARSHALL.

11. On pages 60013 through to 60025, in Table 5.—List of Diagnosis-Related Groups (DRGs), Relative Weighting

Factors, and Geometric and Arithmetic Mean Length of Stay (LOS), DRGs 525,

544, and 572 are corrected to read as follows:

a. Effective October 1, 2006.

DRG	FY 07 final rule post-acute care DRG	FY 07 final rule special pay DRG	MDC	Type	DRG title	Weights	Geometric mean LOS	Arithmetic mean LOS
525	No	No	05	SURG	Other Heart Assist System Implant	2.2268	7.7	14.3
544	Yes	Yes	08	SURG	Major Joint Replacement or Re-attachment of Lower Extremity.	1.9878	4.0	4.4
572	Yes	No	06	MED ..	Major Gastrointestinal Disorders and Peritoneal Infections.	1.3378	5.6	7.1

12. On page 60025 in Table 5.—List of Diagnosis-Related Groups (DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length

of Stay (LOS), the table is corrected by adding the following notes to the end of the table:

a. Effective October 1, 2006.

Note: If there is an asterisk in the “Type” column this means that data is unavailable to calculate weights for these low volume DRGs. Therefore, last year’s weights have been updated based on the percent change in

normalization factors between FY 2006 and FY 2007.

Note: If there is no value or dashes (that is, "----") in either the geometric mean LOS or the arithmetic mean LOS columns, the volume of cases is insufficient to determine a meaningful computation of these statistics.

IV. Discussion of Effective Date and Notice and Comment Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). In addition, a final rule would ordinarily require a 30-day delay in effective date after the date of publication in the **Federal Register**. This correction of the rates published in the FY 2007 IPPS notice does not constitute a rule under the Administrative Procedure Act, because, in our FY 2007 IPPS final rule (71 FR 47870, August 18, 2006), we already published the methodologies and formulas we use for determining the wage index, geographic adjustment factors, and other rates. This notice does not change our methodology or formulas, but merely ensures that our rules are implemented correctly. As this notice is not a rule under the Administrative Procedure Act, no notice of proposed rulemaking or delay in effective date is necessary.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: December 28, 2006.

Ashley Files Flory,

Deputy Executive Secretary to the Department.

[FR Doc. 06–9976 Filed 12–29–06; 1:29 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0525]

Supplements and Other Changes to an Approved Application; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments on issues that FDA should consider when developing revisions to its regulations

regarding chemistry, manufacturing, and controls (CMC) supplements and other changes to approved marketing applications for human drugs. FDA is evaluating how it could revise its regulations to allow for consideration of risk-based approaches based on manufacturing process understanding, including prior knowledge of similar products, and overall quality systems to provide an enhanced risk-based approach to the CMC regulatory process, which would reduce the number of supplements. We will consider the input from the public meeting and comments on the issues presented in this document as we consider whether to revise our regulations.

DATES: The public meeting will be held on February 7, 2007, from 8:30 a.m. to 3:30 p.m. Anyone who wishes to speak at the meeting must register and submit a summary of the presentation by January 24, 2007, and submit an electronic copy of the presentation by January 31, 2007. See section III of the **SUPPLEMENTARY INFORMATION** section of this document for details on how to register. Submit written or electronic comments by March 7, 2007.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Drug Evaluation and Research Conference Room, 7519 Standish Pl., third floor, rm. A, Rockville, MD 20855. There is parking near the building. Photo identification is required to clear building security.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

David J. Cummings, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3525, Rockville, MD 20993–0002, 301–796–2400, e-mail: David.Cummings@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 28, 1999 (64 FR 34608), FDA published a proposed rule to implement section 116 of the Food and Drug Administration Modernization Act (FDAMA)¹ by

¹ Section 116 of FDAMA (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (FDCA) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to

amending certain regulations including § 314.70 (21 CFR 314.70) regarding supplements and other changes to approved human new drug and abbreviated new drug marketing applications. In the **Federal Register** of April 8, 2004 (69 FR 18728), FDA published the final rule (final rule) implementing these changes. Section 314.70, as amended, requires manufacturers to assess the effects of manufacturing changes on the identity, strength, quality, purity, and potency of a drug as those factors relate to the safety or effectiveness of the product, and categorizes all changes beyond the established variations in an approved NDA or ANDA into one of three groups—major, moderate, or minor. Major changes require an applicant to submit and receive FDA approval of a supplement before distribution of the product made with the manufacturing change. Moderate changes require an applicant to submit a supplement at least 30 days before distribution of the product or, in some cases, submit a supplement at the time of distribution. Minor changes require an applicant to notify FDA of the changes in an annual report.

In August 2002, FDA introduced the Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century Initiative (CGMP Initiative, available on the Internet at <http://www.fda.gov/cder/gmp/index.htm>) to enhance and modernize the regulation of pharmaceutical manufacturing and product quality. In September 2004 (after publication of the final rule), FDA published a final report on “Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach” (http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm). As explained in the report, FDA regulates pharmaceutical manufacturing to ensure that the drug supply in the United States is of consistently high quality. Because of critical public health implications of drug manufacturing, FDA traditionally has exercised extensive control over virtually every aspect of the manufacturing process. This regulatory approach has contributed to pharmaceutical companies being reluctant to change their manufacturing processes and equipment. In recent years, significant advances in pharmaceutical manufacturing science, modern quality management systems, and risk management approaches have taken place. This has yielded new tools that

certain approved marketing applications, including new drug applications (NDAs) and abbreviated new drug applications (ANDAs).