Rules and Regulations

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531
RIN 3206–AM25

General Schedule Locality Pay Areas


ACTION: Final rule.

SUMMARY: On behalf of the President’s Pay Agent, the U.S. Office of Personnel Management is issuing final regulations on the locality pay program for General Schedule employees. The regulations, which became applicable on January 1, 2011, established separate locality pay areas for the States of Alaska and Hawaii and extended coverage of the Rest of U.S. locality pay area to include American Samoa, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Territory of Guam, the U.S. Virgin Islands, and all other U.S. possessions listed in 5 CFR 591.205, applicable on the first day of the first pay period that began on or after January 1, 2011.

DATES: Effective on July 7, 2011 we are adopting as a final rule, with minor changes, the interim rule published at 75 FR 60285 on September 30, 2010. Applicability Date: The regulations were applicable on the first day of the first pay period beginning on or after January 1, 2011.

FOR FURTHER INFORMATION CONTACT: Allan Hearne, (202) 606–2838; FAX: (202) 606–4264; e-mail: pay-leave-policy@opm.gov.

SUPPLEMENTARY INFORMATION: Section 5304 of title 5, United States Code, authorizes locality pay for General Schedule (GS) employees with duty stations in the United States and its territories and possessions. The Non-Foreign Area Retirement Equity Assurance Act of 2009 (NAREAA), Public Law 111–84, title XIX, subtitle B (October 28, 2009), extended locality pay to the States of Alaska and Hawaii and the U.S. territories and possessions effective in January 2010. While the statute included a sense of the Congress statement that one locality pay area cover the entire State of Alaska and one cover the entire State of Hawaii, it did not actually establish any new locality pay areas.

Section 5304(f) of title 5, United States Code, authorizes the President’s Pay Agent (the Secretary of Labor, the Director of the Office of Management and Budget, and the Director of the Office of Personnel Management (OPM)) to determine locality pay areas. The boundaries of locality pay areas must be based on appropriate factors, which may include local labor market patterns, commuting patterns, and the practices of other employers. The Pay Agent must give thorough consideration to the views and recommendations of the Federal Salary Council (Council), a body composed of experts in the fields of labor relations and pay policy and representatives of Federal employee organizations. The President appoints the members of the Council, which submits annual recommendations to the Pay Agent about the locality pay program. In its interim rule, the Pay Agent concluded that separate locality pay areas should be established for the States of Alaska and Hawaii because we have non-Federal salary survey data collected by the Bureau of Labor Statistics (BLS) in its National Compensation Survey (NCS) program showing pay disparities between General Schedule (GS) and non-Federal pay well above that for the Rest of U.S. (RUS) locality pay area. Such action also coincides with the sense of the Congress statement in the NAREAA that these locations each be covered by a single separate locality pay area. The Pay Agent also concluded that the other non-foreign areas, which are not covered by the NCS program, should be treated like other locations in the United States where pay levels are lower than in the RUS area, or that cannot be surveyed separately and included them in the RUS area.

Development of New Survey Methodology

In response to earlier requests of the Federal Salary Council, BLS has developed a method for using data from its much larger Occupational Employment Statistics (OES) program in conjunction with National Compensation Survey (NCS) data. The method assesses the impact of level of work on pay using NCS data so that OES data can be used to compare GS and non-Federal pay for the same levels of work in a geographic area as required by the locality pay statute. The President’s Fiscal Year 2011 budget included a proposal to use this new alternative approach for locality pay in order to free up BLS resources for use in other programs while extending the estimation of pay gaps to areas that are not present in the NCS sample. The Federal Salary Council and the Pay Agent plan to use the new OES model in the future.

While BLS does not cover Guam, Puerto Rico, or the U.S. Virgin Islands under the NCS program, BLS does have a robust sample for these locations and for Anchorage and Honolulu under OES. The Federal Salary Council evaluated comparisons of GS and non-Federal pay for these locations before it submitted its views on the interim rule. Here are the results:

<table>
<thead>
<tr>
<th>Location</th>
<th>Non-Federal pay/GS pay disparity (percent)</th>
<th>Location minus RUS disparity (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchorage</td>
<td>53.99</td>
<td>25.85</td>
</tr>
<tr>
<td>Honolulu</td>
<td>39.19</td>
<td>11.05</td>
</tr>
<tr>
<td>Guam</td>
<td>−0.46</td>
<td>−28.60</td>
</tr>
</tbody>
</table>

Comparison of GS and Non-Federal Pay Using OES Data—March 2010
The results indicate that non-Federal pay levels in Anchorage and Honolulu are well above those in the RUS area while non-Federal pay levels in Guam, Puerto Rico, and the U.S. Virgin Islands are well below those in the RUS area.

Federal Salary Council Comments

The Federal Salary Council met during the comment period on the interim regulations and submitted the following comments supporting the Pay Agent’s interim rule:

“The Non-Foreign Area Retirement Equity Assurance Act of 2009 (the Act) extended locality pay to the “non-foreign” areas. The Pay Agent issued an interim regulation on September 30, 2010, making Alaska and Hawaii separate whole-State locality pay areas and adding American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, the U.S. Virgin Islands, and U.S. territories and possessions to the Rest of U.S. locality pay area. The Pay Agent concluded Alaska and Hawaii should be separate areas based on NCS salary surveys in Anchorage and Honolulu that show higher non-Federal pay levels than in the RUS area and a sense of Congress contained in the Act that Alaska and Hawaii should be separate whole-State areas. BLS does not conduct surveys under NCS in any of the other “non-foreign” areas. The Council concurs with the Pay Agent’s action to make Alaska and Hawaii separate whole-State locality pay areas and include the other areas in the RUS locality pay area.

BLS does include Guam, Puerto Rico, and the U.S. Virgin Islands under the OES program and applied its OES model to these locations. The results are included in Attachment 2. Based on the OES model, non-Federal pay levels in these locations are well below those in the RUS area. However, since RUS is an average, it is likely about half of RUS is also below the average. Our policy in the past has been that the RUS locality rate should be the floor; no location should receive less than the RUS rate. We believe this is a good policy and should continue and apply to Guam, Puerto Rico, and the U.S. Virgin Islands.


Comments Received

OPM received 49 comments on the interim rule, including comments from an attorney representing employees in Caraballo v. U.S., Members of Congress representing American Samoa and Guam, and the Guam Federal Executive Association. Comments included:

- Some supported separate whole-State pay areas for Alaska and Hawaii as provided in the regulations.
- Some believe a higher rate should be approved for remote areas in Alaska. (OPM notes, however, that locality pay must be based on pay comparisons, not remoteness.)
- Some believe the statutory cap on locality pay is unfair. (OPM notes, however, that the caps are imposed by statute.)
- Some believe employees in the Northern Mariana Islands and Guam should receive a higher rate than Alaska and Hawaii due to remoteness and isolation. (OPM notes, however, that locality pay must be based on pay comparisons, not remoteness.)
- Some believe Hawaii should receive Washington-Baltimore locality pay. (OPM notes, however, that locality pay survey results show that is not warranted by local labor market rates.)

Many of the comments expressed the view that Pacific locations should receive either the Hawaii or Washington-Baltimore locality pay rate due to the effect of remoteness and isolation from the mainland. We respond in detail below to comments submitted by the attorney, since they expressed similar views and were the most detailed.

Comment 1

“It is my view that including transoceanic non-foreign areas in the Rest of U.S. locality pay area is contrary to the fundamental premise of the Caraballo settlement.”

“The foundation of the Caraballo settlement is the recognition and agreement by the parties that rate-based cost comparisons are insufficient to provide a true picture of the economies of the non-foreign areas, which are remote and isolated from the rest of the country in many ways. This is just as true for salary costs as for living costs.”

OPM Response

We conclude the fundamental premise of Caraballo is equivalent to its foundation. The Caraballo settlement is confined to the former cost-of-living allowance (COLA) program and doesn’t apply to the GS locality pay program. The locality pay statute requires locality pay based on comparisons of GS and non-Federal pay for the same levels of work, 5 U.S.C. 5304, not on the Caraballo settlement, living costs, or a view of the “true picture of the economies.”

Comment 2

“Without an adjustment to account for various conditions which are unique to such areas (including those described below), the living standards afforded by the locality pay rate will be lower than Congress intended.”

OPM Response

We find that Congress did not prescribe a policy to address any particular living standard, did not authorize consideration of living costs in setting locality pay, and did not cite living standards in the locality pay statute. See 5 U.S.C. 5304. The locality pay statute authorizes locality pay to make General Schedule rates of pay “substantially equal (when considered in the aggregate) to the rates paid to non-Federal workers for the same levels of work in the same locality.” 5 U.S.C. 5304. Adding separate adjustments above local labor market rates to account for various conditions which are unique to such areas isn’t contemplated in the locality pay statute and would cause GS rates of pay to be higher than market rates, not “substantially equal when considered in the aggregate.” See 5 U.S.C. 5304.

Comment 3

“If, for administrative reasons, a non-foreign area is to be included in the locality pay area established for a broader region, then the two places should have an affinity of some kind.”

“However, lumping a transoceanic non-foreign area together with Montana and Wyoming makes no sense at all.”

“the choice made in this rule is the least costly for the Government, and
there does not appear to be any other basis for it.”

**OPM Response**

We believe these locations do have an affinity. Based on available salary survey data, pay levels in these locations are low. Both OPM and the Federal Salary Council evaluated available BLS pay data for Guam, Puerto Rico, and the U.S. Virgin Islands and found the comparison of GS to non-Federal pay in those locations to be below the results for the Rest of U.S. locality pay area. In this way, Guam, Puerto Rico, and the U.S. Virgin Islands were treated exactly like a mainland U.S. location where survey results were below RUS—as the Federal Salary Council has recommended, they were included in the RUS locality pay area. Likewise, other locations that cannot be evaluated separately are also included in the RUS area, whether they are remote on the mainland or remote in the Pacific.

**Comment 4**

“An alternative choice of a locality pay area for the transoceanic non-Foreign areas might be the new locality pay area which covers the Hawaiian Islands.”

**OPM Response**

Pay survey findings indicate non-Federal pay levels in Honolulu are higher than those in Guam and the RUS area and thus warrant a separate locality pay area. Pay survey results in Guam indicate low non-Federal pay levels. There is nothing in the pay statute that requires the Government to pay more than warranted by the local labor market. See 5 U.S.C. 5304.

**Comment 5**

“However, in light of the COLA program history, the Washington, D.C. area is a better choice than Hawaii as the locality pay area for other transoceanic non-Foreign areas at the present time.”

and

“The reason for this preference is that the Federal Salary Council has acknowledged the private salary data from both Alaska and Hawaii to be unsatisfactory in certain respects and has urged increased funding for survey enhancements in those areas.”

and

“There is a wealth of statistical data comparing living costs between the non-Foreign areas and Washington, DC, and this data can be used to correlate locality pay rates in the non-Foreign areas (including Hawaii and Alaska) with the rate in Washington, D.C.”

**OPM Response**

The COLA program history is not relevant to the administration of the locality pay program. The COLA statute predates locality pay by 42 years and authorized payments in non-Foreign areas made in consideration of living costs substantially higher than in the District of Columbia or conditions of environment which differ substantially from conditions in the continental United States and warrant payments as a recruitment incentive. See 5 U.S.C. 5304 and 5 U.S.C. 5941. Congress chose to phase out COLA and replace it with locality pay. Public Law 111–84, title XIX, subtitle B (October 28, 2009).

**Comment 6**

“Unfortunately, OPM has provided inadequate notice of this rule, and inadequate opportunity for comments and further investigation with respect to this critical issue.”

**OPM Response**

The comments did not explain what was inadequate about the notice or opportunity for comment. Interim final rules are permitted under the regulatory process if necessary to comply with statutory deadlines. OPM accepted and received comments on the interim rule through November 29, 2010, including the attorney’s comments. The NAREAA required that locality pay areas for COLA areas be established in time for locality payments in January 2011. Public Law 111–84, title XIX, subtitle B (October 28, 2009). OPM published the rule as an interim rule so that the rule could go into effect before January 2011. This timeline constraint was specifically cited in the interim rule. FR Vol. 75 No. 189, page 60285, September 30, 2010. The attorney, and other commenters, are concerned that living cost surveys indicate living costs are high in the COLA areas while pay surveys indicate pay levels are not so high. He adds “However, OPM has made no attempt to reconcile the results of the two approaches, much less to explain the diametrically opposite results they yield.”

**OPM Response**

The locality pay statute bases locality pay on comparisons of General Schedule and non-Federal pay for the same levels of work. 5 U.S.C. 5304, not on living costs, at the heart of the Caraballo settlement. Living costs are one of many factors affecting pay levels in a location. The extent to which living costs affect or do not affect the supply and price of labor is reflected in area labor costs and salary survey results. Other relevant factors affecting labor costs include the number, types, and skill sets of workers in the area, the size and industry composition of employers, the degree of unionization, and a host of other factors. The locality pay statute does not provide for or require a means for OPM or the Pay Agent to reconcile differences between living costs and salary surveys. See 5 U.S.C. 5304.

**Comment 7**

The attorney believes that “Part of the explanation for the divergence in results between salary-cost surveys and living-cost surveys undoubtedly lies in the insularity of the transoceanic areas and the strong racial, ethnic, and cultural ties which bind together the residents of those places and inhibit out-migration in search of better paying jobs elsewhere.”

**OPM Response**

The locality pay statute bases locality pay on comparisons of General Schedule (GS) and non-Federal pay for the same levels of work. 5 U.S.C. 5304. It does not base locality pay on out-migration patterns or racial, ethnic, and cultural ties. 5 U.S.C. 5304.

**Comment 8**

“The locality pay system is not intended to allow the Government to take advantage of depressed conditions in a locality pay area but rather to increase salaries—and thus the performance and retention—of federal workers everywhere in the nation. Yet this rule will have the effect of dragging down the living standards of federal employees in the transoceanic non-Foreign areas.”
The statute bases locality pay on comparisons of General Schedule (GS) and non-Federal pay for the same levels of work in order to make GS and non-Federal pay substantially equal when considered in the aggregate. 5 U.S.C. 5304. It does not require adjusting survey results to compensate for “depressed conditions” whether such conditions are in the Pacific and attributable to distance from the mainland or ethnic factors, in Detroit and due to conditions in the auto industry, or in areas of the U.S. impacted by natural disasters. 5 U.S.C. 5304. Likewise, the locality pay statute does not guarantee any particular living standard. 5 U.S.C. 5304. Likewise, the locality pay statute does not guarantee any particular living standard. 5 U.S.C. 5304. It does not require adjusting survey results to compensate for “depressed conditions” whether such conditions are in the Pacific and attributable to distance from the mainland or ethnic factors, in Detroit and due to conditions in the auto industry, or in areas of the U.S. impacted by natural disasters. 5 U.S.C. 5304. Likewise, the locality pay statute does not guarantee any particular living standard. 5 U.S.C. 5304.

Comment 10

The attorney believes “**” this rule is not only arbitrary, capricious, and an abuse of discretion under the Administrative Procedure Act, but it is also unlawfully discriminatory against racial and ethnic minorities which have disproportionately large presences **” in the transoceanic areas **”**. Other commenters made similar comments.

**OPM Response**

Based on available data, non-Federal pay levels in these locations are low. Both OPM and the Federal Salary Council evaluated available BLS pay data for Guam, Puerto Rico, and the U.S. Virgin Islands and found the comparison of GS to non-Federal pay in those locations to be below the results for the Rest of U.S. locality pay area. In this way, Guam, Puerto Rico, and the U.S. Virgin Islands were treated exactly like a mainland location where survey results were below RUS. As the Federal Salary Council has recommended, they were included in the RUS locality pay area. Likewise, other locations that cannot be evaluated separately are also included in the RUS area, whether they are remote on the mainland or remote in the Pacific.

Impact and Implementation

This rule affects rates of pay for about 44,100 civilian white-collar employees in the States of Alaska and Hawaii, American Samoa, the Commonwealths of Puerto Rico and the Northern Mariana Islands, Guam, the U.S. Virgin Islands, and other U.S. possessions. Under the rule, approved GS locality pay rates are higher than in the RUS locality pay area for employees in Alaska and Hawaii. Federal civilian white-collar employees in the U.S. territories and possessions are covered by the RUS GS locality pay rate.

Clarification and Updates

During the comment period, we noted that the definition of “Continental United States” in section 531.602 and reference to continental U.S. in the definition of employee are no longer needed, so we are removing this out-of-date language. We are also taking this publication opportunity to update the locality pay caps in section 531.606 to be consistent with current law.

**Executive Order 13563 and Executive Order 12866**

The Office of Management and Budget has reviewed this rule in accordance with E.O. 13563 and 12866.

**Paperwork Reduction Act**

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13.

**Regulatory Flexibility Act**

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

**List of Subjects in 5 CFR Part 531**


**John Berry,**

Director.

Accordingly, OPM is adopting as a final rule, with minor changes, the interim rule published at 75 FR 60285 on September 30, 2010 and is amending 5 CFR part 531 as follows:

**PART 531—PAY UNDER THE GENERAL SCHEDULE**

1. The authority citation for part 531 continues to read as follows:

**Authority:** 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Public Law 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335 and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304 and 5305; E.O. 12860, 58 FR 63261, 3 CFR, 1993 Comp., p. 682; and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

2. In §531.602, remove the definition of Continental United States and revise paragraph (1) in the definition of employee. The revision reads as follows:

**§531.602 Definitions.**

* * * * * * * * * * * * *

**Employee** * * * * * * * * * * * * *

(1) An employee in a position to which 5 U.S.C. chapter 53, subchapter III, applies, including a GM employee, and whose official worksite is located in a locality pay area; and

* * * * * * * * * * * * *

3. In §531.603, paragraph (b) is revised to read as follows:

**§531.603 Locality pay areas.**

* * * * * * * * * * * * *

(b) The following are locality pay areas for the purposes of this subpart:

(1) Alaska—consisting of the State of Alaska;

(2) Atlanta-Sandy Springs-Gainesville, GA-AL—consisting of the Atlanta-Sandy Springs-Gainesville, GA-AL CSA;


(4) Buffalo-Niagara-Cattaraugus, NY—consisting of the Buffalo-Niagara-Cattaraugus, NY CSA;

(5) Chicago-Naperville-Michigan City, IL-IN-WI—consisting of the Chicago-Naperville-Michigan City, IL-IN-WI CSA;

(6) Cincinnati-Middletown-Wilmington, OH-KY-IN—consisting of the Cincinnati-Middletown-Wilmington, OH-KY-IN CSA;

(7) Cleveland-Akron-Elyria, OH—consisting of the Cleveland-Akron-Elyria, OH CSA;

(8) Columbus-Marion-Chillicothe, OH—consisting of the Columbus-Marion-Chillicothe, OH CSA;

(9) Dallas-Fort Worth, TX—consisting of the Dallas-Fort Worth, TX CSA;

(10) Dayton-Springfield-Greenville, OH—consisting of the Dayton-Springfield-Greenville, OH CSA;


(12) Detroit-Warren-Flint, MI—consisting of the Detroit-Warren-Flint, MI CSA, plus Lenawee County, MI;

(13) Hartford-West Hartford-Willimantic, CT-MA—consisting of the Hartford-West Hartford-Willimantic, CT CSA, plus the Springfield, MA MSA and New London County, CT;

(14) Hawaii—consisting of the State of Hawaii;

(15) Houston-Baytown-Huntsville, TX—consisting of the Houston-Baytown-Huntsville, TX CSA;

(16) Huntsville-Decatur, AL—consisting of the Huntsville-Decatur, AL CSA;
(17) Indianapolis-Anderson-Columbus, IN—consisting of the Indianapolis-Anderson-Columbus, IN CSA, plus Grant County, IN;
(18) Los Angeles-Long Beach-Riverside, CA—consisting of the Los Angeles-Long Beach-Riverside, CA CSA, plus the Santa Barbara-Santa Maria-Goleta, CA MSA and all of Edwards Air Force Base, CA;
(19) Miami-Fort Lauderdale-Pompano Beach, FL—consisting of the Miami-Fort Lauderdale-Pompano Beach, FL MSA, plus Monroe County, FL;
(20) Milwaukee-Racine-Waukesha, WI—consisting of the Milwaukee-Racine-Waukesha, WI CSA;
(21) Minneapolis-St Paul-St Cloud, MN-WI—consisting of the Minneapolis-St. Paul-St. Cloud, MN-WI CSA;
(22) New York-Newark-Bridgeport, NY-NJ-CT-PA—consisting of the New York-Newark-Bridgeport, NY-NJ-CT-PA CSA, plus Monroe County, PA, Warren County, NJ, and all of Joint Base McGuire-Dix-Lakehurst; 
(24) Phoenix-Mesa-Scottsdale, AZ—consisting of the Phoenix-Mesa-Scottsdale, AZ MSA;
(25) Pittsburgh-New Castle, PA—consisting of the Pittsburgh-New Castle, PA CSA;
(26) Portland-Vancouver-Hillsboro, OR-WA—consisting of the Portland-Vancouver-Hillsboro, OR-WA MSA, plus Marion County, OR, and Polk County, OR;
(27) Raleigh-Durham-Cary, NC—consisting of the Raleigh-Durham-Cary, NC CSA, plus the Fayetteville, NC MSA, the Goldsboro, NC MSA, and the Federal Correctional Complex Butner, NC; 
(28) Richmond, VA—consisting of the Richmond, VA MSA;
(29) Sacramento—Arden-Arcade—Yuba City, CA-NV—consisting of the Sacramento—Arden-Arcade—Yuba City, CA-NV CSA, plus Carson City, NV; 
(30) San Diego-Carlsbad-San Marcos, CA—consisting of the San Diego-Carlsbad-San Marcos, CA CSA, plus the Salinas, CA MSA and San Joaquin County, CA;
(32) Seattle-Tacoma-Olympia, WA—consisting of the Seattle-Tacoma-Olympia, WA CSA, plus Whatcom County, WA;
(33) Washington-Baltimore-Northern Virginia, DC-MD-VA-WV-PA—consisting of the Washington-Baltimore-Northern Virginia, DC-MD-VA-WV CSA, plus the Hagerstown-Martinsburg-Monroe, MD-WV MSA, the York-Hanover-Gettysburg, PA CSA, and King George County, VA; and
(34) Rest of U.S.—consisting of those portions of the United States and its territories and possessions as listed in 5 CFR 591.205 not located within another locality pay area.

4. In § 531.606—
   a. Revise paragraph (b)(1);
   b. Redesignate paragraph (b)(2) and (b)(3) as (b)(3) and (b)(4), respectively;
   c. Add a new paragraph (b)(2); and
   d. Revise newly designated paragraph (b)(4).

The revisions and addition read as follows:

531.606 Maximum limits on locality rates.

(a) * * *

(b)(1) A locality rate for an employee in a category of positions described in 5 U.S.C. 5304(h)(1)(A) and 5304(h)(1)(B) may not exceed the rate for level III of the Executive Schedule.

(2) A locality rate for an employee in a category of positions described in 5 U.S.C. 5304(h)(1)(C) may not exceed—
   (i) The rate for level III of the Executive Schedule, when the positions are not covered by an appraisal system certified under 5 U.S.C. 5307(d); or
   (ii) The rate for level II of the Executive Schedule, when the positions are covered by an appraisal system certified under 5 U.S.C. 5307(d).

(4) If initial application of paragraph (b)(3) of this section otherwise would reduce an employee’s existing locality rate, the employee’s locality rate is capped at the higher of—
   (i) The amount of the employee’s locality rate on the day before paragraph (b)(3) of this section was initially applied; or
   (ii) The rate for level IV of the Executive Schedule.

* * * * *

[FR Doc. 2011–13993 Filed 6–6–11; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 320

[Docket No. FDA–2010–D–0482]

Guidance for Industry and Investigators on Enforcement of Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and investigators entitled “Enforcement of Safety Reporting Requirements for INDs and BA/BE Studies.” This guidance is intended to inform sponsors and investigators of FDA’s intent to exercise enforcement discretion regarding the reporting requirements in the final rule, “Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans” (75 FR 59935, September 29, 2010), until September 28, 2011. This action is being taken in response to requests from sponsors to extend the March 28, 2011, effective date of the final rule. FDA expects all sponsors and investigators to be in compliance with the new regulations no later than September 28, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–