

identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: September 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-23508 Filed 9-12-03; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002D-0094]

#### Guidance for Industry on Investigational New Drug Application Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer." This guidance clarifies FDA's policy on exemption from investigational new drug application (IND) requirements for studies of marketed cancer drug or biological products. This guidance is intended to decrease the submission of unnecessary IND exemptions.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one

self-addressed adhesive label to assist that office in processing your requests. This guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Grant A. Williams, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5758, or

Patricia Keegan, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5093.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer." Exemption from IND regulation of certain studies of marketed drugs is allowed under 21 CFR 312.2(b)(1). Along with other criteria outlined in the regulation, investigations that involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product are not exempt from the requirements for an IND. This guidance discusses the pertinent regulations relating to exemption of INDs, the risk/benefit determination in the practice of oncology, FDA's policy for determining exemption status based on risk, and specific examples of studies generally considered exempt.

In the **Federal Register** of April 9, 2002 (67 FR 17078), FDA announced the availability of a draft version of this guidance and gave interested persons an opportunity to submit comments through June 10, 2002. The agency received comments from investigators at two institutions and took the comments into consideration when finalizing the guidance. However, the final guidance includes no substantive changes, only editorial and clarifying changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on IND exemptions based on risk for studies of lawfully marketed cancer drug or biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 5, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0399]

#### Guidance for Industry on Pentetate Calcium Trisodium and Pentetate Zinc Trisodium for Treatment of Internal Contamination with Plutonium, Americium, or Curium; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that we (FDA) have concluded that pentetate calcium trisodium (Ca-DTPA) and pentetate zinc trisodium (Zn-DTPA), when produced under conditions specified in approved new drug applications (NDAs), can be found

to be safe and effective for the treatment of internal contamination with plutonium, americium, or curium to increase the rates of elimination. We encourage the submission of NDAs for Ca-DTPA and Zn-DTPA drug products. We are also announcing the availability of a guidance for industry entitled "Calcium-DTPA and Zinc-DTPA Drug Products—Submitting a New Drug Application." This guidance is intended to assist manufacturers who plan to submit NDAs for Ca-DTPA and Zn-DTPA.

**ADDRESSES:** Submit NDAs to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Room, 12229 Wilkins Ave., Rockville, MD 20857. Submit requests for copies of draft labeling to the Division of Medical Imaging and Radiopharmaceutical Drug Products (HFD-160), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510. Copies of the reports referred to in this document will be on display at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (address given previously). Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Kyong Kang, Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

###### **A. Plutonium, Americium, and Curium**

Plutonium, americium, and curium are transuranium radioactive elements of the actinide series. They are products of nuclear bombardment and are found in the fallout from the detonation of nuclear weapons and the waste from nuclear power plants. These elements are used in various types of research.

All isotopes of plutonium, americium, and curium are radioactive.

Contamination with plutonium, americium, or curium can occur through a variety of routes including ingestion, inhalation, and/or wounds. Contamination can cause serious illness or death when high radiation absorbed doses are delivered to critical organs. Lower doses have been associated with the development of cancer long after exposure. In addition to concerns about exposure to plutonium, americium, or curium in industrial and research environments, contamination by radioactive elements such as these, is of particular concern because of their potential use in a radiological dispersal device (RDD), commonly called a "dirty bomb." An RDD is a conventional explosive or bomb containing radioactive material. The conventional bomb is used as a means to spread radioactive material. An RDD is not a nuclear weapon and does not involve a nuclear explosion. Significant amounts of radioactive material, particularly plutonium, could also be spread by the detonation of an improvised nuclear device by terrorists. The extemporized design and construction of such a terrorist weapon could lead to an incident where only a small portion of the weapon's plutonium is consumed in the atomic reaction, and the rest of the plutonium is spread through the air by the explosion of the device. There are currently no approved treatments for internal contamination with plutonium, americium, or curium.

###### **B. Ca-DTPA and Zn-DTPA**

Diethylenetriaminepentaacetate (DTPA) is a ligand that acts as a chelator with a very high affinity for plutonium, americium, and curium. The calcium salt of DTPA is known as pentetate calcium trisodium and is referred to as Ca-DTPA. The zinc salt of DTPA is known as pentetate zinc trisodium and is referred to as Zn-DTPA.<sup>1</sup>

For several decades, Ca-DTPA and Zn-DTPA have been used investigational to enhance the excretion of plutonium, americium, and curium from the body by means of ion exchange, chelation, and, ultimately, excretion through the urine. Because DTPA has a very high affinity for these transuranium elements, when it comes in contact with such elements, the

calcium or zinc ions of Ca-DTPA and Zn-DTPA drugs are readily exchanged for the transuranium elements. The transuranium-DTPA complex is then rapidly excreted in the urine. There are currently no approved NDAs for drug products containing Ca-DTPA or Zn-DTPA.

Ca-DTPA and Zn-DTPA in sterile aqueous solution have been used under investigational new drug applications (INDs) held by the Radiation Emergency Assistance Center/Training Site (REAC/TS). REAC/TS is part of the Oak Ridge Associated Universities (ORAU). ORAU operates the Oak Ridge Institute for Science and Education under a contract with the Department of Energy. The INDs are for treatment of contamination resulting from nuclear power or other industrial accidents.

Traditional clinical trials have not been conducted because it would be unethical to deliberately expose patients to radiation; it would also be unethical to withhold potential beneficial medications from patients who have been accidentally exposed. Instead, under these INDs, accidentally exposed patients were treated empirically and the findings were reported in the literature as observational studies.

REAC/TS has retained the medical case reports on 646 patients treated with Ca-DTPA and Zn-DTPA for radiation contamination during the last 40 years. To facilitate the development and ultimate approval of Ca-DTPA and Zn-DTPA drug products, we have reviewed the medical reports on the patients in the REAC/TS database and reviewed the available published literature. This notice announces our conclusions about the safety and effectiveness of Ca-DTPA and Zn-DTPA drug products, and it is addressed primarily to persons interested in submitting NDAs for Ca-DTPA or Zn-DTPA drug products.

##### **II. Safety and Effectiveness of Ca-DTPA and Zn-DTPA Drug Products**

We have concluded that Ca-DTPA and Zn-DTPA drug products, when produced under conditions specified in approved NDAs, can be found to be safe and effective for the treatment of patients with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination. As described in section II.A of this document, our conclusion is based on our review of medical reports in the REAC/TS database.

We encourage the submission of NDAs for both Ca-DTPA and Zn-DTPA drug products. If you are interested in submitting NDAs for these products, please contact the Center for Drug

<sup>1</sup> For purposes of this document Ca-DTPA refers only to pentetate calcium trisodium, which has an empirical formula of  $\text{Na}_3\text{CaC}_{14}\text{H}_{18}\text{N}_3\text{O}_{10}$  and the Chemical Abstracts Service (CAS), registry number 12111-24-9. Zn-DTPA refers only to pentetate zinc trisodium, which has an empirical formula of  $\text{Na}_3\text{ZnC}_{14}\text{H}_{18}\text{N}_3\text{O}_{10}$  and the CAS registry number 125833-02-5.

Evaluation and Research's (CDER's) Division of Medical Imaging and Radiopharmaceutical Drug Products for a copy of the draft labeling (see **ADDRESSES**). We also recommend that you consult the guidance entitled "Calcium-DTPA and Zinc-DTPA Drug Products—Submitting a New Drug Application," which is being made available with this notice (see section V of this document).

#### *A. Basis for Finding of Safety and Effectiveness*

We have reviewed medical reports in the REAC/TS database and have determined that Ca-DTPA and Zn-DTPA drug products, when produced under conditions specified in an approved NDA, can be found to be safe and effective for treatment of patients with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination. Our conclusion is supported by our review of reports in the literature, which provided information consistent with that in the REAC/TS database.

Administration of a loading dose of Ca-DTPA followed by maintenance treatment with Zn-DTPA increases the rate of elimination of these radioactive elements from the body and is expected to decrease the risk of death and major morbidity from radiation complications.

In reaching our determination on the effectiveness of Ca-DTPA and Zn-DTPA, we evaluated reports from the REAC/TS database on 646 patients who received one or more doses of these drugs during the last 40 years. Ca-DTPA was administered either by inhalation or by intravenous injection. Zn-DTPA was administered by intravenous injection. Data on the type of transuranium element and amount of urine elimination were available for detailed analysis from 18 patients. In these patients, administration of Ca-DTPA by inhalation or intravenous injection of a 1-gram (g) dose of Ca-DTPA in a 5 milliliter (mL)-sterile aqueous solution increased the rate of radiation elimination in the urine an average of 39-fold. Maintenance doses of Zn-DTPA administered once daily resulted in continued elimination of radiation.

Some adverse effects were identified as resulting from Ca-DTPA and Zn-DTPA administration. The primary adverse effects of Ca-DTPA administration were the elimination from the body of endogenous essential trace metals, particularly zinc, but also including magnesium and manganese. The endogenous trace metal decreases occurred after treatment for several days and appeared to increase when the

drugs were given in divided doses over 1 day. Although Zn-DTPA is also believed to decrease serum magnesium and manganese, no serious toxicity has been observed with the administration of Zn-DTPA in humans or animals. In patients undergoing administration of Ca-DTPA or Zn-DTPA drug products, blood levels of these endogenous trace metals should be followed closely and can be treated with nutritional supplements.

In pregnant animals, multiple doses of Ca-DTPA are associated with fetal malformations and fetal death. Similar effects on animal fetuses were not seen with Zn-DTPA. As a result, Zn-DTPA should be used to begin treatment in pregnant patients. However, if Zn-DTPA is not available, the risks related to radiation contamination should be weighed against the risks of Ca-DTPA to the mother and fetus.

Intravenous administration of Ca-DTPA is recommended and should be used if the route of radioactive contamination is not known or if multiple routes of contamination are possible. In patients whose contamination is only by inhalation within the preceding 24 hours, Ca-DTPA administered as a single loading dose by nebulized inhalation is an alternative route of administration. However, administration of Ca-DTPA by inhalation may irritate some patients, especially those with a history of respiratory disorders. In these patients, the intravenous route can be used. Other rare adverse events are discussed in the published literature and in the draft labeling we have prepared.

#### *B. Labeling for Ca-DTPA and Zn-DTPA*

We have prepared draft labeling for Ca-DTPA supplied as 1 g in a 5 mL-sterile aqueous solution for administration either by inhalation (with a 1:1 dilution with saline and delivered by nebulization) or intravenous injection. We have also prepared draft labeling for Zn-DTPA supplied as 1 g in a 5-mL sterile aqueous solution for intravenous injection. You can submit this draft labeling as part of an NDA for Ca-DTPA or Zn-DTPA drug product that relies on our findings of safety and effectiveness. The draft labeling reflects our conclusion on the potential safety and effectiveness of Ca-DTPA and Zn-DTPA for treatment of patients with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination. The draft labeling may need to be modified if you submit an NDA for either Ca-DTPA or Zn-DTPA and there is not an approved NDA for the other DTPA drug

product, or the other drug product is otherwise unavailable. If you wish to change the labeling to include a different or broader indication or different dosage, or if you wish to make any other significant changes to the draft labeling, you should provide, as part of your NDA, additional literature or other studies to support your requested changes. If you submit an NDA for either a Ca-DTPA or Zn-DTPA drug product that is not based on our findings of the safety and effectiveness of Ca-DTPA and Zn-DTPA, you cannot use the draft labeling because it is based on our review of the REAC/TS database and published literature. If you submit such an NDA, your labeling must be based on the safety and effectiveness data contained in your NDA.

The draft labeling for NDAs based on our review of the REAC/TS database and published literature is available on the Internet at <http://www.fda.gov/cder/drug/infopage/dtpa/default.htm>. You may also contact CDER's Division of Medical Imaging and Radiopharmaceutical Drug Products for a copy of the draft labeling (see **ADDRESSES**).

### **III. Conclusions**

We have determined that Ca-DTPA and Zn-DTPA can be safe and effective for treatment of patients with known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination. We encourage the submission of NDAs for Ca-DTPA and Zn-DTPA drug products. The requirement under 21 U.S.C. 355(b)(1) for full reports of investigations to support these NDAs may be met by citing this notice and the published literature we relied on in preparing this notice. For a list of this published literature see section V of this document. A list of the published literature and reprints of the reports will be available for public inspection in the Division of Dockets Management (see **ADDRESSES**). It is unnecessary to submit copies and reprints of the reports from the listed published literature. We invite applicants to submit any other pertinent studies and literature of which they are aware.

### **IV. Availability of a Guidance**

#### *A. Notice of Availability*

In this document, we are also announcing the availability of a guidance for industry entitled "Ca-DTPA and Zn-DTPA Drug Products—Submitting a New Drug Application." The guidance is intended to assist manufacturers who plan to submit NDAs for Ca-DTPA and Zn-DTPA.

This guidance is being issued as a level 1 guidance consistent with our good guidance practices regulation (21 CFR 10.115). It is being implemented immediately without prior public comment because we believe it is in the interest of the public health to communicate this information to the public as quickly as possible. However, we welcome comments on the guidance, and if comments are submitted, we will review them and revise the guidance if appropriate. The guidance represents our current thinking on issues associated with the submission of NDAs for Ca-DTPA and Zn-DTPA drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### B. Comments

Interested persons may, at any time, submit written comments on the guidance to the Division of Dockets Management (see **ADDRESSES**). Two copies of any mailed comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### C. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

#### V. Published Literature on the Safety and Effectiveness of Ca-DTPA and Zn-DTPA

The published literature we have relied on in making the determinations regarding Ca-DTPA and Zn-DTPA contained in this notice is listed in this section of this document. Copies of the published literature will be on display in the Division of Dockets Management (see **ADDRESSES**) and can be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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Dated: September 8, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### Open Meeting, Board of Visitors for the National Fire Academy

**AGENCY:** U.S. Fire Administration (USFA), FEMA, Emergency Preparedness and Response, Homeland Security.

**ACTION:** Notice of open meeting.

**SUMMARY:** In accordance with section 10 (a) (2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, FEMA announces the following committee meeting:

*Name:* Board of Visitors (BOV) for the National Fire Academy.

*Dates of Meeting:* October 2-4, 2003.

*Place:* Building H, Room 300, National Emergency Training Center, Emmitsburg, Maryland.

*Time:* October 2, 2003, 10:30 a.m.-5 p.m.

October 3, 2003, 8:30 a.m.-5 p.m.

October 4, 2003, 9 a.m.-12 noon.

*Proposed Agenda:* October 2-4, Review National Fire Academy Program Activities.

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public with seating available on a first-come, first-served basis. Members of the general public who plan to attend the meeting should contact the Office of the Superintendent, National Fire Academy, U.S. Fire Administration, 16825 South Seton Avenue, Emmitsburg, MD 21727, (301) 447-1117, on or before September 26, 2003.

Minutes of the meeting will be prepared and will be available for public viewing in the Office of the U.S. Fire Administrator, U.S. Fire Administration, Federal Emergency Management Agency, Emmitsburg, Maryland 21727. Copies of the minutes will be available upon request within 60 days after the meeting.

Dated: September 5, 2003.

**R. David Paulison,**

*U.S. Fire Administrator, Director of the Preparedness Division.*

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4728-N-03]

### Notice of Certain Operating Cost Adjustment Factors for 2004

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Publication of the 2004 Operating Cost Adjustment Factors (OCAFs) for Section 8 rent adjustments at contract renewal under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA), as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, and under the Low-Income Housing Preservation and Resident Homeownership Act of 1990 (LIHPRA) Projects assisted with Section 8 Housing Assistance Payments.

**SUMMARY:** This notice establishes annual factors used in calculating rent adjustments under section 524 of MAHRA as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, and under LIHPRA.

**EFFECTIVE DATE:** February 11, 2004.

#### FOR FURTHER INFORMATION CONTACT:

Regina Aleksiewicz, Housing Project Manager, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, Office of Multifamily Housing, 451 Seventh Street, SW., Washington, DC 20410-8000; telephone (202) 708-3000; extension 2600 (This is not a toll-free number). Hearing-or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1-800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### I. Operating Cost Adjustment Factors (OCAFs)

Section 514(e)(2) of the FY 1998 HUD Appropriations Act, requires HUD to establish guidelines for rent adjustments based on an operating cost adjustment factor (OCAF). The legislation requiring HUD to establish OCAFs for LIHPRA projects and projects with contract renewals under section 524 of MAHRA is similar in wording and intent. HUD has therefore developed a single factor to be applied uniformly to all projects utilizing OCAFs as the method by which rents are adjusted.

Additionally, section 524 of the Act gives HUD broad discretion in setting OCAFs—referring simply to “operating cost factors established by the Secretary.” The sole exception to this grant of authority is a specific

requirement that application of an OCAF shall not result in a negative rent adjustment. OCAFs are to be applied uniformly to all projects utilizing OCAFs as the method by which rents are adjusted upon expiration of the term of the contract. OCAFs are applied to project contract rent less debt service.

An analysis of cost data for FHA-insured projects showed that their operating expenses could be grouped into nine categories: wages, employee benefits, property taxes, insurance, supplies and equipment, fuel oil, electricity, natural gas, and water and sewer. Based on an analysis of these data, HUD derived estimates of the percentage of routine operating costs that were attributable to each of these nine expense categories. Data for projects with unusually high or low expenses due to unusual circumstances were deleted from analysis.

States are the lowest level of geographical aggregation at which there are enough projects to permit statistical analysis. Additionally, no data were available for the Western Pacific Islands. Data for Hawaii was therefore used to generate OCAFs for these areas.

The best current measures of cost changes for the nine cost categories were selected. The only categories for which current data are available at the state level are for fuel oil, electricity, and natural gas. Current price change indices for the other six categories are only available at the national level. The Department had the choice of using dated state-level data or relatively current national data. It opted to use national data rather than data that would be two or more years older (*e.g.*, the most current local wage data are for 1996). The data sources for the nine cost indicators selected were as follows:

*Labor Costs*—3/02 to 3/03 Bureau of Labor Statistics (BLS), Employment Cost Index, Private Sector Wages and Salaries Component at the National Level.

*Employment Benefit Costs*—3/02 to 3/03 BLS Employment Cost Index, Employee Benefits at the National Level.

*Property Taxes*—3/02 to 3/03 BLS Consumer Price Index, All Items Index.

*Goods, Supplies, Equipment*—3/02 to 3/03 BLS Producer Price Index, Finished Goods Less Food and Energy.

*Insurance*—3/02 to 3/03 BLS Consumer Price Index, Tenant and Household Residential Insurance Index.

*Fuel Oil*—Energy Information Agency, 2000 to 2001 annual average state prices for #2 distillate residential fuel oil (U.S. average change was used for states with too little fuel oil consumption to have values).

*Electricity*—Energy Information Agency, 2000 to 2001 annual average