

enforcement authorities can be adapted to assist the FTC in combating cross-border fraud?

**7. Consumer and Business Education Partnerships**

The FTC frequently works with businesses and industry to provide education on consumer issues. The FTC seeks comment on ways it can engage with the private sector to provide education about cross-border fraud:

How can the FTC, other public entities, and the private sector partner to better educate consumers and businesses about ways to thwart cross-border fraud?

**Request To Participate as a Panelist in the Workshop**

If you wish to participate as a panelist in the workshop, you must notify the FTC in writing by January 24, 2003. Such requests should be made either by mail to the Secretary of the FTC or by e-mail to *crossborderfraud@ftc.gov*. A request to participate as a panelist should be captioned "Public Workshop: Public/Private Partnerships to Combat Cross-Border Fraud—Request to Participate, P035302." Each person is asked to include in the request the topic area for participation, a statement of expertise in or knowledge of the issues relevant to that topic, and contact information, including a telephone number, and email address. Unless submitting by email, an original and two copies of each document should be submitted. Panelists will be notified of their selection by January 31, 2003.

Using the following criteria, FTC staff will select a limited number of panelists to participate in the workshop:

1. The party has expertise in or knowledge of the issues that are the focus of the workshop.

2. The party's participation would promote a balance of interests being represented at the workshop.

3. The party has been designated by one or more interested parties who timely file requests to participate as a party who shares group interests with the designator(s).

In addition, there will be time during the workshop for those not serving as panelists to ask questions.

**Form and Availability of Comments**

To facilitate the discussion, the FTC requests that interested persons submit written comments on the general subject of the workshop and in response to any questions posed on issues that could be addressed. Comments should be captioned "Public Workshop: Public/Private Partnerships to Combat Cross-Border Fraud—Comment, P035302."

Persons sending written comments should submit an original and two copies of each document. To enable prompt review and public access, paper submissions should include a version on diskette in PDF, ASCII, WordPerfect, or Microsoft Word format. Diskettes should be labeled with the name of the person, and the name and version of the word processing software used to create the document. Alternatively, comments may be emailed to *crossborderfraud@ftc.gov*.

Written comments will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and FTC regulations, 16 CFR part 4.9, Monday through Friday between the hours of 8:30 a.m. and 5 p.m. at the Public Reference Room 130, Federal Trade Commission, 600

Pennsylvania Avenue, NW., Washington, DC 20580. This notice and, to the extent technologically possible, all comments will also be posted on the FTC Web site, *http://www.ftc.gov*.

By direction the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 02-32991 Filed 12-30-02; 8:45 am]

**BILLING CODE 6750-01-M**

**FEDERAL TRADE COMMISSION**

**Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules**

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvement Acts of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

Trans No.	Acquiring	Acquired	Entities
<b>Transactions Granted Early Termination—09/30/2002</b>			
20021184 .....	Ripplewood Partners, L.P. ....	Robert H. Baker .....	All American Chevrolet, Inc. Bob Baker Automotive, Inc. Bob Baker Automotive, Inc. Bob Baker Imports, Inc. Bob Baker Volkswagen, Inc. El Cajon Luxury Cars, Inc. University Ford, Inc. Comdisco Holding Company Inc. Legrand S.A.
20021187 .....	Berkshire Hathaway Inc. ....	Comdisco Holding Company Inc. ....	Enron Corp. (Debtor-in-Possession) ...
20021189 .....	Lumina Parent S.A.R.L. ....	Schneider Electric S.A. ....	Gate Gourmet Holding AG.
20021193 .....	FdG Capital Partners LLC .....	Enron Corp. (Debtor-in-Possession) ...	Arizona Mail Order, Inc.
20021196 .....	TPG Partners III, L.P. ....	SAirGroup AG .....	Bedford Fair Apparel, Inc.
20021198 .....	J.P. Morgan Chase & Co. ....	Federated Department Stores, Inc. ....	Family Farm Gifts, Inc. Figi's Gifts, Inc. Figi's Inc. Figi's Mail Order Gifts, Inc. LM&B Catalog, Inc. PC Flowers & Gifts.com LLC.
20021200 .....	Nippon Yusen Kabushiki Kaisha .....	Christos N. Kritikos .....	Ceres Terminals Incorporated.

Trans No.	Acquiring	Acquired	Entities
20021201 .....	TransCanada Pipelines Limited .....	Limestone Electron Trust .....	Equipvest LLC. Manchief Power Company LLC.
<b>Transactions Granted Early Termination—10/01/2002</b>			
20021056 .....	E.I. duPont de Nemours and Company	ChemFirst Inc .....	ChemFirst Inc.
<b>Transactions Granted Early Termination—10/03/2002</b>			
20021197 .....	SPX Corporation .....	Vance International, Inc. Employee Stock Ownership Plan.	Vance International, Inc.
<b>Transactions Granted Early Termination—10/04/2002</b>			
20021152 .....	International Business Machines Cor- poration.	ACCESS360 .....	ACCESS360.
20021163 .....	Medtronic, Inc .....	Spinal Dynamics Corporation .....	Spinal Dynamics Corporation.
20021183 .....	Warburg, Pincus Equity Partners, L.P.	Centerpulse Ltd .....	Sulzer Intra Therapeutics Inc.
20021202 .....	General Electric Company .....	Castle Harlan Partners III. L.P. ....	Ion Track, Inc.
20021204 .....	Blue Holdings Corp .....	Vivendi Environment, S.A .....	U.S. Filter Distribution Group, Inc.
20021206 .....	Provimplux Investments S.A .....	Intalenergia S.p.A. ....	Provimi
20021207 .....	Atlantic Equity Partners, III, LP .....	Carl F. Paul, c/o Golfsmith Inter- national Inc.	Golfsmith International, Inc.
20021209 .....	Linsalata Capital Partners Fund IV, L.P.,	H.I.G. Investment Group L.P. ....	Potpourri Holdings, Inc.
20021210 .....	J.P. Morgan Chase & Co .....	Blue Holdings Corporation .....	Blue Holdings Corporation.
20021211 .....	Thomas H. Lee Equity Fund, V. L.P ...	Blue Holdings Corp. ....	Blue Holdings Corp.
20021213 .....	Cooperative Centrale Raiffeisen- Boerenleenbank B.A.	CIT Group Inc. ....	Picker Financial Group, L.L.C.
20021214 .....	Cooperative Centrale Raiffeisen- Boerenleenbank B.A.	Koninklijke Philips Electronics N.V. ....	Picker Financial Group, L.L.C.
20021222 .....	James D. Reigle Trust dated Decem- ber 15, 1978.	Illinois Tool Works Inc .....	Premark WB Holdings, Inc.  The West Bend Company.
<b>Transactions Granted Early Termination—10/08/2002</b>			
20021216 .....	Avery Dennison Corporation .....	L&E Packaging, LLC .....	L&E Packaging, LLC.
<b>Transactions Granted Early Termination—10/10/2002</b>			
20021224 .....	Home Depot, Inc. (The) .....	Brian J. Whitehead .....	DuraFloors, Inc. Floor of Florida, LLC. Floors, Inc. Supply Expo, L.P.
20021226 .....	Home Depot, Inc .....	Arvada Hardwood Floor Company .....	Arvada Hardwood Floor Company. Furniture to Go, L.P. L.P. Home Solutions by Arvada Hardwood LLC.
20030001 .....	New England Medical Center, Inc .....	Lifespan of Massachusetts, Inc .....	New England Medical Center Hos- pitals, Inc.
<b>Transactions Granted Early Termination—10/15/2002</b>			
20021180 .....	US Investigations Services, Inc .....	VS&A Communications Partners II, L.P.	The Official Information Company.
20021217 .....	Combe Incorporated .....	Byrwood Partners II L.P. ....	J.B. Williams Company, Inc.
20030004 .....	Finmeccanica S.p.A .....	Olivetti S.p.A. ....	Telespazio S.p.A.
20030007 .....	Harrah's Entertainment, Inc .....	LAD LLC .....	Louisiana Downs, Inc.
20030010 .....	Bain Capital Fund VII, L.P .....	Georgia-Pacific Corporation .....	UWW Holdings, Inc.
20030011 .....	Amer Group Plc .....	Illinois Tool Works Inc .....	Precor Incorporated. Precor Products Limited. Precor Sportgerate GmbH.
20030015 .....	Waddell & Reed Financial, Inc .....	Paul G. Desmarais .....	Ivy Acquisition Corp.
<b>Transactions Granted Early Termination—10/16/2002</b>			
20030008 .....	Oak Investment Partners X .....	New SAC .....	XIOtech Corporation.
20030009 .....	Professor Kurt Jenny .....	Kosan Biosciences, Inc .....	Kosan Biosciences, Inc.
20030018 .....	TWI Holdings, Inc .....	Dag Landvik c/o Fagerdala Industri AB	Tempur World, Inc.
20030019 .....	TA IX L.P .....	TWI Holdings, Inc .....	TWI Holdings, Inc.
20030020 .....	Enzon, Inc .....	Elan Corporation, plc .....	Elan Corporation, plc.
20030022 .....	Bookham Technology plc .....	Nortel Networks Corporation .....	Nortel Networks Corporation.

Trans No.	Acquiring	Acquired	Entities
20030024 .....	GTCR Fund VII, L.P .....	Getronics NV .....	Getronics Government Solutions, L.L.C.
<b>Transactions Granted Early Termination—10/18/2002</b>			
20030021 .....	Gryphon Partners II, L.P .....	Nobel Learning Communities, Inc .....	Nobel Learning Communities, Inc.
<b>Transactions Granted Early Termination—10/22/2002</b>			
20030028 .....	AdvancePCS .....	Accordant Health Services, Inc .....	Accordant Health Services, Inc.
20030032 .....	General Motors Corporation .....	Royal Dutch Petroleum Company .....	Shell Capital Inc.
20030035 .....	Tom T. Gores .....	Koninklijke Philips Electronics N.V .....	HC Products, LLC.
<b>Transactions Granted Early Termination—10/23/2002</b>			
20021223 .....	Berkshire Hathaway Inc .....	Doris and Jay Christopher .....	The Pampered Chef, Ltd.
<b>Transactions Granted Early Termination—10/24/2002</b>			
20021205 .....	AIG Highstar Capital, L.P .....	The Williams Companies, Inc .....	Western Frontier Pipeline Company, LLC.
20030014 .....	Carlyle Partners III, L.P .....	Invensys plc .....	Williams Gas Pipelines Central, Inc. Brook Hansen France Sales S.A.R.L. Brook Hansen, S.A. Changzhou Hansen Jiangling Transmissions Co. Ltd. Clarkson Industries Inc. M.C.C. Holding B.V. Prager Incorporated. Rexnord A/S. Rexnord AB. Rexnord Corporation. Rexnord Correntes Ltda. Rexnord do Brasil Industrial Ltda. Rexnord France S.A.R.L. Rexnord GmbH. Rexnord Marbett SpA. Rexnord NV. Stephan GmbH. Eastern Financial Systems, Inc.
20030025 .....	Fidelity National Financial, Inc .....	Eastern Financial Systems, Inc .....	Eastern Financial Systems, Inc.
20030031 .....	Blue Point Capital Partners, L.P .....	Generation Capital Partners, L.P .....	LVI Holding Corporation.
20030037 .....	Documentum, Inc .....	eRoom Technology, Inc .....	eRoom Technology, Inc.
<b>Transactions Granted Early Termination—10/25/2002</b>			
20030041 .....	The Alpine Group, Inc .....	Superior TeleCom Inc .....	DNE Systems Inc. Superior Telecommunications Inc. Texas SUT Inc.
<b>Transactions Granted Early Termination—10/29/2002</b>			
20020861 .....	Nucor Corporation .....	Birmingham Steel Corporation .....	Birmingham Southeast, LLC. Port Everglades Steel Corporation.
20021126 .....	Carl C. Icahn .....	XO Communications, Inc. ....	XO Communications, Inc
20030030 .....	Plum Creek Timber Company, Inc .....	Stora Enso Oyj .....	Stora Enso North America Corporation.
20030046 .....	Cooperatieve Centrale Raiffeisen-Boerenleenbank B.A. ....	Occidental Petroleum Corporation .....	Occidental Overseas Operations, Inc.
<b>Transactions Granted Early Termination—10/30/2002</b>			
20030003 .....	Eaton Corporation .....	Dana Corporation .....	Dana Corporation.
<b>Transactions Granted Early Termination—10/31/2002</b>			
20021225 .....	Bergemann GmbH .....	ABB Ltd .....	ABB Inc. ABB Meeting Holdings Ltd.
20030023 .....	Buckeye Partners, L.P .....	Colonial Pipeline Co .....	Colonial Pipeline Co.
<b>Transactions Granted Early Termination—11/01/2002</b>			
20030039 .....	Kelso Investments Associates VI, L.P .....	BCO Holding Company .....	BCO Holding Company.
20030043 .....	IOI Corporation Berhad .....	Unilever N.V .....	Loders Crokiaan Business.
20030044 .....	The Stanley Works .....	Russell C. Best and Mariea L. Best, as husband and wife.	Best Lock Corporation.

Trans No.	Acquiring	Acquired	Entities
20030045 .....	AGCO Corporation .....	SPX Corporation .....	Sunflower Manufacturing Company, Inc.
<b>Transactions Granted Early Termination—11/04/2002</b>			
20030048 .....	Triton PCS Holdings, Inc .....	AT&T Wireless Services, Inc .....	AT&T Wireless PCS Inc.
20030049 .....	ENEL S.p.A .....	Central Vermont Public Service Corporation.	Gauley River Management Corporation.
20030050 .....	Banque Federate des Banques .....	Arnhold and S. Bleichroeder Holdings, Inc.	Gauley River Power Partners, L.P.
20030051 .....	Arnhold and S. Bleichroeder Holdings, Inc.	Banque Federale Des Banquest Populaires.	Arnhold and S. Bleichroeder, Inc.
20030053 .....	Brown & Brown, Inc .....	Donald E. Martin .....	Natexis Banques Populaires.
20030054 .....	Clayton, Dubilier & Ride Fund VI Limited Partnership.	Kinko's Inc .....	Chartered Financial Services Corporation.
20030056 .....	Microsoft Corporation .....	Vicinity Corporation .....	Kinko's Inc.
20030057 .....	Adventist Health System Sunbelt .....	Adventist Health Mid-America, Inc .....	Vicinity Corporation.
20030058 .....	GS Capital Partners 2000, L.P .....	R.H. Donnelley Corporation .....	Adventist Health Mid-America, Inc.
20030060 .....	GILDEMEISTER Aktiengesellschaft .....	ThyssenKrupp AG .....	R.H. Donnelley Corporation.
20030061 .....	Bucher Industries AG .....	Knight Manufacturing Corporation .....	ThyssenKrupp Metal Cutting GmbH.
			Knight Manufacturing Corporation.
<b>Transactions Granted Early Termination—11/05/2002</b>			
20030063 .....	GROWMARK, Inc .....	Agway, Inc .....	Agway, Inc.
<b>Transactions Granted Early Termination—11/07/2002</b>			
20030033 .....	NetIQ Corporation .....	PentaSafe Security Technologies, Inc	PentaSafe Security Technologies, Inc.
20030047 .....	Lake Carnegie, LLC .....	Walcott Partners, L.P .....	Celtics Basketball, L.P.
20030065 .....	ONEOK, Inc .....	Southern Union Company .....	Southern Union Company.
20030070 .....	Lucent Technologies Inc .....	Solectron Corporation .....	Solectron Corporation.
<b>Transactions Granted Early Termination—11/12/2002</b>			
20030081 .....	Spectrum Equity Investors IV, L.P .....	RCN Corporation .....	RCN Telecom Services, Inc.
<b>Transactions Granted Early Termination—11/13/2002</b>			
20030082 .....	RF Micro Devices, Inc .....	Resonext Communications, Inc .....	Resonext Communications, Inc.
<b>Transactions Granted Early Termination—11/15/2002</b>			
20030042 .....	Liberty Media Corporation .....	ACTV, Inc .....	ACTVN, Inc.
<b>Transactions Granted Early Termination—11/19/2002</b>			
20030083 .....	Insight Communications Company, Inc	AT&T Corp .....	InterMedia Partners Southeast.
20030086 .....	Temasek Holdings (Private) Limited .....	Global Crossing Ltd .....	Global Crossing Ltd. (New).
20030087 .....	Hutchison Whampoa Limited .....	Global Crossing Ltd .....	Global Crossing Ltd. (New).
20030089 .....	Grant Prideco, Inc .....	Schlumberger Limited .....	Reed-Hycalog Operating, L.P.
20030090 .....	Schlumberger Limited .....	Grant Prideco, Inc .....	Grant Prideco, Inc.
20030096 .....	Health Management Associates, Inc .....	Monterra Health System, Inc .....	Aracoma Medical Foundation, Inc.
20030097 .....	General Electric Company .....	Cablevision System Corporation .....	The Logan Medical Foundation.
20030098 .....	Nautic Partners, V, L.P .....	Summit Venture IV, L.P .....	Bravo Company.
20030101 .....	LifePoint Hospitals, Inc .....	Monterra Health System, Inc .....	Bravo Holding Corporation.
			Bravo II Holding Corporation.
			HRI Holdings Corp.
			Aracoma Medical Foundation, Inc.
			The Logan Medical Foundation.
<b>Transactions Granted Early Termination—11/20/2002</b>			
20030068 .....	First Reserve Fund IX, L.P .....	Quanta Services, Inc .....	Quanta Services, Inc.
20030094 .....	Mitsubishi Corporation .....	Newco Corporation .....	Newco Corporation.
20030107 .....	The Berwind Company LLC .....	Hunt Corporation .....	Hunt Corporation.
<b>Transactions Granted Early Termination—11/21/2002</b>			
20020432 .....	Wal-Mart Stores, Inc .....	Supermercados Amigo, Inc .....	Supermercados Amigo, Inc.
20030064 .....	KSM Aquisition Company, L.P .....	Metromedia International Group, Inc .....	Snapper, Inc.

Trans No.	Acquiring	Acquired	Entities
<b>Transactions Granted Early Termination—11/22/2002</b>			
20030078 .....	King Pharmaceuticals, Inc .....	Meridian Medical Technologies, Inc ....	Meridian Medical Technologies, Inc.
20030084 .....	DRS Technologies, Inc .....	Paravant Inc .....	Paravant Inc.
20030088 .....	Guidant Corporation .....	Novartis AG .....	Novartis AG.
20030115 .....	Meredith Corporation .....	PRIMEDIA, Inc .....	PRIMEDIA, Inc.
<b>Transactions Granted Early Termination—11/25/2002</b>			
20030092 .....	Northern Trust Corporation .....	Deutsche Bank AG .....	Deutsche Asset Management (Australia) Ltd. Deutsche Asset Management Investment Services Ltd. Deutsche Asset Management Japan Limited. Deutsche Asset Management Life & Pensions Ltd. Deutsche Asset Management Limited. Deutsche Asset Management, Inc. Deutsche Bank Trust Company Americas. Deutsche Investment Management Americas Inc. Deutsche Trust Bank Limited. Deutsche Trust Company. Deutsche Unit Trust Managers Limited.
20030103 .....	Prudential Financial, Inc .....	TMW Real Estate Group, LLC .....	TMW Investments, Inc. TMW Real Estate Group, LLC. TMW Real Estate Management, Inc. Carlton Company.
20030110 .....	James E. Stephenson .....	Carlton Company .....	Carlton Company.
20030116 .....	SSA Investor, LLC .....	Infinium Software, Inc .....	Infinium Software, Inc.
20030118 .....	Fisherv, Inc. ....	Electronic Data Systems Corporation ..	EDS Information Services, LLC. EDS Resource Management Corporation.
20030120 .....	SECOM Co., Ltd .....	Futurelogic Incorporated .....	Futurelogic Incorporated.
<b>Transactions Granted Early Termination—11/27/2002</b>			
20020840 .....	Hitachi, Ltd .....	International Business Machines Corporation.	Holdco.
20030059 .....	BAE Systems plc .....	Condor Pacific Industries, Inc .....	Condor Pacific Industries, Inc.
<b>Transactions Granted Early Termination—12/02/2002</b>			
20030075 .....	Borland Software Corporation .....	TogetherSoft Corporation .....	TogetherSoft Corporation.
<b>Transactions Granted Early Termination—12/03/2002</b>			
20030108 .....	Community Health Systems, Inc .....	HCA, Inc .....	HCA, Inc.
20030109 .....	Community Health Systems, Inc .....	Methodist Healthcare .....	Methodist Healthcare.
20030111 .....	DG Foods Income Fund .....	The Estate of Arthur M. Goldberg .....	Di Giorgio Corporation.
20030117 .....	Cathay Financial Holding Co., Ltd .....	United World Chinese Commercial Bank.	United World Chinese Commercial Bank.
20030122 .....	Chemtrade Logistics Income Fund .....	Clariant AG .....	Clariant (Canada) Inc. Clariant Corporation.
20030139 .....	KAP Global Publishers S.A .....	Wolters Kluwer nv .....	Kluwer Academic Publishers B.V.
20030142 .....	Safeguard Scientifics, Inc .....	Alliance Consulting Group Associates, Inc.	Alliance Consulting Group Associates, Inc.
20030144 .....	Morgan Stanley Dean Witter Capital Partners IV, L.P.	Baptist Health System .....	Baptist Health System.
20030158 .....	Superior Propane Income Fund .....	Sterling Chemicals Holdings, Inc .....	Sterling (Sask) Holdings Ltd. Sterling Canada, Inc. Sterling Chemicals Acquisitions, Inc. Sterling NRO, Ltd. Sterling Pulp Chemicals Fuzhou, Ltd. Sterling Pulp Chemicals US, Inc. Sterling Pulp Chemicals, Inc. Sterling Pulp Chemicals, Inc.
<b>Transactions Granted Early Termination—12/04/2002</b>			
20030091 .....	National Oilwell, Inc .....	Hydralift ASA .....	Hydralift ASA.

Trans No.	Acquiring	Acquired	Entities
20030123 .....	Mr. Reinhard Mohn .....	Clive J. Davis, c/o J Entertainment LLC.	J Records LLC.

## Transactions Granted Early Termination—12/05/2002

20030102 .....	Kenneth A. Hendricks .....	William Davidson .....	Wm. Cameron & Co.
20030136 .....	State Street Corporation .....	Deutsche Bank AG .....	InterSec Research Corp.
20030146 .....	Vito Modesto Rodriguez Rodriguez .....	Dean Foods Company .....	Garrido y Compania, LLC.
		Neva Plastics Manufacturing Corp.	
		Suiza Dairy II.	
		Suiza Fruit Corp.	
20030148 .....	Eurohypo Aktiengesellschaft .....	Allianz Aktiengesellschaft .....	Allianz Aktiengesellschaft.
			Dresdner Bank AG.
20030150 .....	Wellspring Capital Partners III, L.P. ....	John C. Vatterott Family Trust .....	Vatterott Educational Centers, Inc.
20030152 .....	ProQuest Company .....	bigchalk.com.inc. ....	bigchalk.com.inc.

## Transactions Granted Early Termination—12/06/2002

20030153 .....	E.ON AG .....	Bergemann GmbH .....	Bergemann GmbH.
20030168 .....	CIT Group Inc .....	Isuzu Motors Limited .....	IMAC OT.
20030170 .....	Bonita Bay Holdings, Inc .....	Abbott Laboratories .....	Abbott Laboratories.

**FOR FURTHER INFORMATION CONTACT:**

Sandra M. Peay or Renee A. Hallman  
Contact Representative, Federal Trade  
Commission, Premerger Notification  
Office, Bureau of Competition, Room  
303, Washington, DC 20580, (202) 326-  
3100.

By Direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 02-32992 Filed 12-30-02; 8:45 am]

BILLING CODE 6750-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96D-0041]

#### International Conference on Harmonisation; Draft Guidance on Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In the **Federal Register** of May 19, 1997 (62 FR 27470), FDA published the guidance entitled "Clinical Safety Data

Management: Periodic Safety Update Reports for Marketed Drugs" (ICH E2C guidance), which recommends a unified standard for the format, content, and reporting frequency for postmarketing periodic safety update reports for drug and biological products. This draft guidance, an addendum to the ICH E2C guidance of May 19, 1997, provides additional information on the content and format of PSURs, including clarification of the objectives, general principles, and model for PSURs. The draft guidance is intended to help harmonize collection and submission of postmarketing clinical safety data. **DATES:** Submit written or electronic comments on the draft guidance by January 24, 2003.

**ADDRESSES:** You may submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the draft 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, 301-827-3844, FAX: 888-CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Regarding the guidance: Min Chen, Center for Drug Evaluation and Research (HFD-430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3159, or Miles Braun, Center for Biologics (HFM-220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6090.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

**SUPPLEMENTARY INFORMATION:****I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH