

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.

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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
Transactions Granted Early Termination—09/30/2002			
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.
Transactions Granted Early Termination—10/01/2002			
20021056	E.I. duPont de Nemours and Company	ChemFirst Inc	ChemFirst Inc.
Transactions Granted Early Termination—10/03/2002			
20021197	SPX Corporation	Vance International, Inc. Employee Stock Ownership Plan.	Vance International, Inc.
Transactions Granted Early Termination—10/04/2002			
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	Provimlux 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.
Transactions Granted Early Termination—10/08/2002			
20021216	Avery Dennison Corporation	L&E Packaging, LLC	L&E Packaging, LLC.
Transactions Granted Early Termination—10/10/2002			
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.
Transactions Granted Early Termination—10/15/2002			
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.
Transactions Granted Early Termination—10/16/2002			
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.
Transactions Granted Early Termination—10/18/2002			
20030021	Gryphon Partners II, L.P	Nobel Learning Communities, Inc	Nobel Learning Communities, Inc.
Transactions Granted Early Termination—10/22/2002			
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.
Transactions Granted Early Termination—10/23/2002			
20021223	Berkshire Hathaway Inc	Doris and Jay Christopher	The Pampered Chef, Ltd.
Transactions Granted Early Termination—10/24/2002			
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.
Transactions Granted Early Termination—10/25/2002			
20030041	The Alpine Group, Inc	Superior TeleCom Inc	DNE Systems Inc. Superior Telecommunications Inc. Texas SUT Inc.
Transactions Granted Early Termination—10/29/2002			
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.
Transactions Granted Early Termination—10/30/2002			
20030003	Eaton Corporation	Dana Corporation	Dana Corporation.
Transactions Granted Early Termination—10/31/2002			
20021225	Bergemann GmbH	ABB Ltd	ABB Inc. ABB Meeting Holdings Ltd.
20030023	Buckeye Partners, L.P	Colonial Pipeline Co	Colonial Pipeline Co.
Transactions Granted Early Termination—11/01/2002			
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.
Transactions Granted Early Termination—11/04/2002			
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.
Transactions Granted Early Termination—11/05/2002			
20030063	GROWMARK, Inc	Agway, Inc	Agway, Inc.
Transactions Granted Early Termination—11/07/2002			
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.
Transactions Granted Early Termination—11/12/2002			
20030081	Spectrum Equity Investors IV, L.P	RCN Corporation	RCN Telecom Services, Inc.
Transactions Granted Early Termination—11/13/2002			
20030082	RF Micro Devices, Inc	Resonext Communications, Inc	Resonext Communications, Inc.
Transactions Granted Early Termination—11/15/2002			
20030042	Liberty Media Corporation	ACTV, Inc	ACTVN, Inc.
Transactions Granted Early Termination—11/19/2002			
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.
			Bravo Company.
			Bravo Holding Corporation.
20030098	Nautic Partners, V, L.P	Summit Venture IV, L.P	Bravo II Holding Corporation.
20030101	LifePoint Hospitals, Inc	Monterra Health System, Inc	HRI Holdings Corp.
			Aracoma Medical Foundation, Inc.
			The Logan Medical Foundation.
Transactions Granted Early Termination—11/20/2002			
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.
Transactions Granted Early Termination—11/21/2002			
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
Transactions Granted Early Termination—11/22/2002			
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.
Transactions Granted Early Termination—11/25/2002			
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.
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.
Transactions Granted Early Termination—11/27/2002			
20020840	Hitachi, Ltd	International Business Machines Corporation.	Holdco.
20030059	BAE Systems plc	Condor Pacific Industries, Inc	Condor Pacific Industries, Inc.
Transactions Granted Early Termination—12/02/2002			
20030075	Borland Software Corporation	TogetherSoft Corporation	TogetherSoft Corporation.
Transactions Granted Early Termination—12/03/2002			
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.
Transactions Granted Early Termination—12/04/2002			
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.

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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