

an additional 60 hours (4 questions × 15 hours each) for generic companies for a total of 99 hours (39 hours + 60 hours).

Now that the Commission has added a question for innovator companies concerning citizen petitions, which it also estimates will require approximately 15 hours to answer, the lower-end estimate is approximately 100 hours for innovator companies as well as generic companies. The revised, high-end of the estimated range (500 hours) recognizes that some companies (approximately 30 percent of innovator companies and generic companies) will have to produce information for more than three drug products, with fewer than five percent of the companies having to produce information on more than 10 drug products. At the same time, the upper-end estimate, though based on this higher volume, also recognizes inherent economies of scale for the process of organizing, identifying, and retrieving information responsive to these requests.

The estimated burden of answering the questions and producing documents per respondent on a functional basis breaks down as follows:

	Hours
Organize document and information retrieval .....	20–50
Identify requested information .....	20–200
Retrieve responsive information ...	25–100
Copy requested information .....	10–50
Prepare response .....	25–100
	100–500

The cumulative hours burden to produce documents sought and prepare the response will be between 9,000 hours (100 hours × 90 companies) and 45,000 hours (500 hours × 90 companies).

*Associated Labor Cost:* It is not possible to calculate precisely the labor costs associated with answering the questions and producing the documents requested, as responses will entail participation by management and/or support staff at various compensation levels among many different companies. Individuals among some or all of those labor categories may be involved in the information collection process. Based on Geneva's comments, staff has increased the dollar figure per hour to reflect the use of outside legal counsel

along with mid-management personnel for handling most (an assumed 90 percent) of the tasks involved to gather and produce the responsive information. For such labor costs, we estimate an average hourly wage of \$250/hour. In addition, staff estimates an average hourly wage of \$10 for the labor of clerical employees who will copy the responsive materials. Thus, the labor costs per company should range between \$22,600 [(90 hours × \$250/hour) + (10 hours × \$10/hour)] and \$113,000 [(450 hours × \$250/hour) + (50 hours × \$10/hour)], with approximately 70 of the 100 companies (70 percent × 70 generic companies plus 70 percent × 30 innovator companies) averaging approximately \$22,600 to respond to information requests.

Assuming the remaining 30 companies average approximately \$67,800 each in labor costs (the mean within the estimated range), then total estimated labor cost is \$3,616,000 ((70 × \$22,600) + (30 × \$67,800)). By comparison, for example, the Commission alleged that Abbott paid Geneva a sum of \$4.5 million per month to keep the generic version of Hytrin off the market.<sup>39</sup> Thus, the Commission believes that the estimated cost is reasonable in light of the size of the markets involved, the potential consumer harm, and Congressional interest in the area.

Geneva estimates that the burden will be "in excess of \$300,000" to respond to the information collection request as proposed. Geneva Comment at 2. The Commission believes Geneva's estimate is based on a misunderstanding of the scope of the information collection request. First, the Commission has clarified the language of Request 1 to exclude agreements not intended to be covered by the request. Second, the Commission has significantly shortened the time period (by four years) for which it seeks such documents. Third, for each request, a company will only have to produce documents and information about specific drug products that are listed in each company's information collection request, rather than for "all products as to which the generic company has made a Paragraph IV certification." Geneva Comment at 3. Thus, Commission staff continues to believe that the estimates provided above are reasonable.

*Estimated capital/other non-labor costs:* The capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may require that respondents retain copies of the information provided to the Commission, industry members should already have in place the means to store information of the volume requested. In addition, respondents may have to purchase office supplies such as file folders, computer diskettes, photocopier toner, or paper in order to comply with the Commission's requests. Staff estimates that each respondent will spend \$500 for such costs regarding the information request, for a total additional non-labor cost burden of \$45,000 (\$500 × 90 companies).

By direction of 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 Improvements Act 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 #	Acquiring	Acquired	Entities
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**TRANSACTIONS GRANTED EARLY TERMINATION—01/22/2001**

20011197 .....	The Pantry, Inc .....	East Coast Oil Company .....	East Coast Oil Company.
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<sup>39</sup> See note 7.

Trans #	Acquiring	Acquired	Entities
20011273 .....	Neptune Orient Lines Limited .....	Oak Hill Partners, L.P .....	New Logistics Holdings Corp., e-Fulfillment Corp.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—01/23/2001</b>			
20011255 .....	CRH plc .....	Carl Lizza, Jr .....	Mt. Hope Rock Products, Inc.
20011268 .....	Sulzer AG .....	Intra Therapeutics, Inc .....	IntraTherapeutics, Inc.
20011281 .....	SCP Pool Corporation .....	Hughes Supply, Inc .....	Allstate Pool Supply, Inc.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—01/24/2001</b>			
20011238 .....	Newport Corporation .....	Kensington Laboratories, Inc .....	Kensington Laboratories, Inc.
20011239 .....	David S. Harris .....	Newport Corporation .....	Newport Corporation.
20011240 .....	Paul E. Bacchi .....	Newport Corporation .....	Newport Corporation.
20011241 .....	Paul S. Filipski .....	Newport Corporation .....	Newport Corporation.
20011249 .....	Lightbridge, Inc .....	Corsair Communications, Inc .....	Corsair Communications, Inc.
20011259 .....	Frank Lyon Jr .....	U.S. Bancorp .....	U.S. Bancorp.
20011274 .....	Professor Kurt Jenny .....	OSI Pharmaceuticals, Inc .....	OSI Pharmaceuticals, Inc.
20011275 .....	Avaya Inc .....	VPNet Technologies, Inc .....	VPNet Technologies, Inc.
20011276 .....	Loyal Trust No. 1 .....	Berkley Petroleum Corp .....	Berkley Petroleum Corp.
20011280 .....	Internet Capital Group, Inc .....	AssetTRADE.com, Inc .....	AssetTRADE.com, Inc.
20011282 .....	B.N. Bahadur .....	Pep Guide LLC .....	Lightsource Parent Corporation.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—01/26/2001</b>			
20011029 .....	Cook Inlet Region, Inc .....	Pocket Communications, Inc., debtor-in-possession.	DCR PCS, Inc. Pocket Communications, Inc., debtor-in-possession.
20011160 .....	Bouygues S.A .....	Henry S. Branscome .....	Branscome Concrete, Inc.
20011209 .....	i2 Technologies, Inc .....	Boston Ventures Limited Partner- ship V.	EC-Content, Inc. Trade Service Corporation.
20011262 .....	Triad Hospitals, Inc .....	Hillcrest Healthcare System .....	SouthCrest L.L.C.
20011294 .....	Citigroup Inc .....	Chase Industries Inc .....	Chase Industries Inc.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—01/29/2001</b>			
20001728 .....	El Paso Energy Corporation .....	The Coastal Corporation .....	The Coastal Corporation.
20011264 .....	Six Flags, Inc .....	Anheuser-Busch Companies, Inc ..	Sea World of Ohio.
20011269 .....	Stronach Trust .....	Hilton Group plc .....	Ladbroke Racing Pennsylvania Inc./Sports Broad- casting, Inc.
20011285 .....	Paul G. Allen .....	TechTV, LLC .....	TechTV, LLC.
20011290 .....	Deutsche Post AG .....	DHL International Limited .....	DHL International Limited.
20011291 .....	Deutsche Post AG .....	DHL Worldwide Express, Inc .....	DHL Worldwide Express, Inc.
20011297 .....	Amcort Limited .....	CNC Containers Corporation .....	CNC Containers Corporation.
20011304 .....	Kyocera Corporation .....	Windward Capital Associates, L.P ..	Tycom Corporation.
20011311 .....	Thomson multimedia S.A .....	Carlton Communications plc .....	Carlton Communications Investments.
20011313 .....	Liberty Mutual Holding Company ..	Liberty Mutual Fire Insurance Company.	Liberty Mutual Fire Insurance Company.
20011314 .....	Liberty Mutual Holding Company ..	Employers Insurance of Wausau Mutual Holding Company.	Employers Insurance of Wausau Mutual Holding Company.
20011317 .....	J.P. Morgan Chase & Co .....	Advanta Corp .....	Advanta Corp.
20011318 .....	Allen B. Morgan, Jr .....	Regions Financial Corporation .....	Regions Financial Corporation.
20011319 .....	Regions Financial Corporation .....	Morgan Keegan, Inc .....	Morgan Keegan, Inc.
20011322 .....	BBA Group PLC .....	General Dynamics Corporation .....	Gulfstream Aerospace Services Corporation.
20011323 .....	Mr. Raul Alarcon, Jr .....	International Church of the Four- square Gospel.	KSFG-FM Station.
20011341 .....	North American Metals, Ltd .....	Birmingham Steel Corporation .....	American Steel and Wire Corporation. Birmingham Steel Corporation.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—01/30/2001</b>			
20011309 .....	Kaydon Corporation .....	William J. & Alice M. Chorkey .....	ACE Controls International, Inc. ACE Controls, Inc.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—01/31/2001</b>			
20011261 .....	Nextel Communications, Inc .....	Motorola, Inc .....	Motorola, Inc.
20011299 .....	Hitachi, Ltd .....	OpNext, Inc .....	OpNext, Inc.
20011301 .....	Clarity Partners, L.P. .....	OpNext, Inc .....	OpNext, Inc.
20011307 .....	Carlyle Partners III, L.P .....	Connecticut Health Foundation, Inc.	Connecticare Holding Company, Inc.
20011325 .....	Olivetti S.p.A .....	Empresa Nacional Telecomunicaciones.	Empresa Nacional de Telecomunicaciones.

Trans #	Acquiring	Acquired	Entities
<b>TRANSACTIONS GRANTED EARLY TERMINATION—02/01/2001</b>			
20011222 .....	CIENA Corporation .....	Cyras Systems, Inc .....	Cyras Systems, Inc.
<b>TRANSACTIONS GRANTED EARLY TERMINATION—02/22/2001</b>			
20011327 .....	Hit Entertainment PLC .....	Lyrick Corporation .....	Big Feats L.P. Lyons Partnership L.P.

**FOR FURTHER INFORMATION CONTACT:**

Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, D.C. 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

### Centers for Disease Control and Prevention

#### The Committee on Immunization Registry Standards and Electronic Transactions and the American Immunization Registry Association Sponsored Meeting of Software Vendors for Healthcare Providers: Meeting

*Name:* Meeting with software vendors for healthcare providers sponsored by the Committee on Immunization Registry Standards and Electronic Transactions and the American Immunization Registry Association.

*Time and Date:* 10 a.m.–1 p.m., July 12, 2001.

*Place:* Arkansas' Excelsior Hotel, Three Statehouse Plaza, Little Rock, Arkansas 72201, telephone 501-375-5000.

*Status:* Open to the public, including all software vendors for healthcare providers, limited only by the space available. The meeting room accommodates approximately 200 people.

#### Purpose: Immunization Registries Issue Invitation to Vendors of Software for Healthcare Providers

The Committee on Immunization Registry Standards and Electronic Transactions (CIRSET), in cooperation with the American Immunization Registry Association (AIRA), invites vendors of healthcare software systems to participate in a meeting on July 12,

2001, from 10:00 a.m. to 1:00 p.m., in conjunction with the Annual Immunization Registry Conference being held at the Arkansas' Excelsior Hotel in Little Rock, AK. The meeting will explore the potential for two-way data exchange between provider software and state and community immunization registries, as envisioned by CIRSET, AIRA, the Centers for Disease Control and Prevention's National Immunization Program (NIP), and state and local immunization registry programs.

#### Challenge

Immunization registries face technical challenges similar to those faced by most of the healthcare industry today—how to enable communication among numerous disparate systems. Registries have been developed by a number of different entities—managed care organizations, independent software vendors, states, cities, counties, and local communities.

The developers of these registries chose the hardware and software support platforms that worked best within their own systems, but the resulting applications cannot communicate with each other except through expensive, custom interfaces.

Traditionally, these practices have caused vendors of practice management systems to have difficulty implementing immunization record exchange because each immunization registry had a different vision, format, and protocol for data exchange. This problem has been addressed using a national standard for electronic data exchange, Health Level Seven. The standard was used to develop an implementation guide for immunization data exchange entitled, "Implementation Guide for Immunization Data Transactions Using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol," June 1999 (Guide). This Guide is the result of collaboration by a number of immunization registry developers who acknowledge the value of standardized data exchange and are ready to implement data exchange among registries. The Guide defines registry specific messages in detail, showing a

range of fully valued messages that carry a complete complement of immunization data. The Guide also defines a "minimum standard message" that could be implemented by a non-clinical system to communicate with a registry. A minimum amount of data could be saved to a file in a standard HL7 format, creating a batch of updates for the provider to send to the registry on a periodic basis. The minimum message consists of core demographic and vaccine event data elements plus values for additional HL7-required fields. These are defined and examples provided in the Guide.

Differences in interpretations, acceptable codes, and definitions have been resolved by consensus. Registries agree that all will benefit if they adhere to one national standard implementation guide that can be available to both registries and software vendors of provider systems. One vendor explained that, with one national implementation, vendors would be more ready to incorporate it into the clinical or computer-based patient record systems they were building or upgrading. Another vendor advised that, even though his product was strictly a billing system, he believed it would be possible to extract the needed data and save it to a file as services were performed in the clinic. That file could be forwarded to the registry, eliminating the need for redundant data entry. A standard implementation allows vendors to assure their customers of compatibility among all participating systems. Just as importantly, implementing a national standard that is already in use in a large number of healthcare systems can save time and money for all involved parties.

#### The Future

Continuing collaboration to ensure that implementation plans meet messaging requirements will enable registry developers, vaccination providers, and vendors of physician systems to achieve interoperability not previously possible. The core data set, current vaccine and vaccine manufacturers' code sets, and the HL7 immunization messaging