

U.S.C. 1337 (“section 337”), based on a complaint filed by Medytox Inc. of Seoul, South Korea (“Medytox”); Allergan plc of Dublin, Ireland; and Allergan, Inc. of Irvine, California (collectively, “Allergan”) (all collectively, “Complainants”). *See* 84 FR 8112–13 (Mar. 6, 2019). The complaint, as supplemented, alleges a violation of section 337 based upon the importation and the sale in the United States of certain botulinum toxin products, processes for manufacturing or relating to same and certain products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States. *See id.* The notice of investigation names as respondents Daewoong Pharmaceuticals Co., Ltd. (“Daewoong”) of Seoul, South Korea and Evolus, Inc. (“Evolus”) of Irvine, California (collectively, “Respondents”). *See id.* The Office of Unfair Import Investigations (“OUII”) was also a party to the investigation. *See id.*

On December 16, 2020, the Commission found a violation of section 337 based on the misappropriation of Complainants’ trade secrets (including the Medytox manufacturing processes but not the Medytox bacterial strain). *See* 85 FR 83610–11 (Dec. 22, 2020). The Commission issued a limited exclusion order against certain botulinum neurotoxin (“BTX”) products that are imported and/or sold by Respondents Daewoong and Evolus and a cease and desist order against Evolus (collectively, “the remedial orders”). *Id.* The Commission also set a bond during the period of Presidential review in an amount of \$441 per 100U vial of Respondents’ accused products. *Id.*

On February 12, 2021, Complainants filed an appeal from the Commission’s final determination with the Federal Circuit (Appeal No. 21–1653). On the same day, Respondents also filed an appeal from the Commission’s final determination of a violation of section 337 (Appeal No. 21–1654). On February 18, 2021, Complainants and Evolus (collectively, “the Settling Parties”) announced that they had reached a settlement to resolve all pending issues between them.

On March 3, 2021, the Settling Parties filed a joint petition to rescind the remedial orders based on settlement agreements and other confidential agreements between and among several of the Settling Parties. On April 5, 2021, Daewoong filed a response to the Settling Parties’ petition not opposing rescission of the remedial orders and also including a motion for vacatur of the Commission’s final determination. On

April 8, 2021, OUII filed a response in support of the joint petition to rescind. On April 15, 2021, Medytox filed a response in opposition to Daewoong’s motion to vacate the final determination.

On May 3, 2021, the Commission determined to rescind the remedial orders. *See* 86 FR 24665–66 (May 7, 2021). The Commission also issued an indicative ruling that, if the Federal Circuit dismisses the pending appeals as moot, the Commission will vacate its final determination. *See id.* The Commission explained that “if the Federal Circuit finds that the . . . appeals are moot” and “[i]f appellate review for Daewoong is prevented, it would be plainly through happenstance, and vacatur would be warranted to prevent any preclusive effect of the final determination against Daewoong.” *See* Comm’n Op. at 8 (May 3, 2021).

On June 21, 2021, Medytox also reached a settlement agreement with AEON Biopharma (“AEON”). AEON is Daewoong’s exclusive licensee in the United States for therapeutic applications of BTX products, while Evolus is the exclusive licensee for aesthetic applications. Consequently, as Medytox stated before the Federal Circuit, “the result of the two settlements is that Medytox has now resolved its disputes with and granted licenses to the two companies that hold the exclusive rights to distribute Daewoong’s BTX products in the United States.” *See* ECF 69, Medytox Statement of Non-Opposition at 2 (Fed. Cir. Docket No. 21–1653); ECF 68, Medytox Letter at 1 (Fed. Cir. Docket No. 21–1653). Thus, Medytox did not oppose the Commission’s and Daewoong’s motions to dismiss the appeals as moot and no longer opposes vacatur of the Commission’s final determination upon remand. On July 26, 2021, the Federal Circuit issued an order dismissing the appeals “to the extent that the appeals are deemed moot” and remanding “the matter . . . for the Commission to address vacatur of its final determination.” *Medytox v. ITC*, No. 21–1653, Order at 2 (Fed. Cir. July 26, 2021).

In accordance with the Commission’s May 3, 2021 indicative ruling of vacatur and the Commission’s reasoning related thereto, and in view of the Federal Circuit’s dismissal of the related appeals as moot, the Commission hereby vacates on remand its final determination. Commissioner Karpel does not join the Commission’s decision to vacate. As she has previously stated, the Commission’s decision to exercise its discretion to grant the extraordinary remedy of vacatur requires an analysis, based on a

complete record and after having heard from all parties on the issue, that includes a careful balancing of the equities, including with respect to the public interest. *See* Comm’n Op. at 9–10 n.15 (May 3, 2021). Commissioner Karpel does not consider that such an analysis was done when the Commission issued its indicative ruling regarding vacatur, *see id.*, or on remand.

The Commission’s vote on this determination took place on October 28, 2021.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission’s Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 28, 2021.

Lisa Barton,

Secretary to the Commission.

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DEPARTMENT OF JUSTICE

[OMB Number 1110–0058]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of an Approved Collection; National Incident-Based Reporting System (NIBRS)

AGENCY: Federal Bureau of Investigation (FBI), Department of Justice (DOJ).

ACTION: 60-Day notice and request for comments.

SUMMARY: The Criminal Justice Information Services (CJIS) Division, FBI, DOJ, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act (PRA) of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 3, 2022.

FOR FURTHER INFORMATION CONTACT: All comments, suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to the Crime and Law Enforcement Statistics (formerly the Crime Statistics Management) Unit Chief, Amy C. Blasher, FBI, CJIS Division, Module D–1 1000 Custer Hollow Road, Clarksburg, West Virginia, 26306.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the FBI, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether, and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses).

Overview of This Information Collection

1. *Type of Information Collection:*

Revision of an approved collection

2. *The Title of the Form/Collection:*

National Incident-Based Reporting System

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is 1110-0058. The applicable component within the DOJ is the CJIS Division in the FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Federal, state, local, and tribal law enforcement agencies (LEAs).

Abstract: Under Title 28, United States Code, section (§) 534(a) and (c); the USA Patriot Improvement and Reauthorization Act of 2005, Public Law 109-177 (March 9, 2006) H.R. 3199: Section 307 (e) Reporting of Cargo Theft; the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008; and the Matthew Shepard and James Byrd, Jr., Hate Crimes Prevention Act (2009), § 4708, this collection requests incident data from federal, state, local, and tribal LEAs in order for the FBI Uniform Crime Reporting (UCR) Program to serve as the national clearinghouse for the collection and dissemination of incident data and to release these statistics in the following publications: *Crime in the United*

States, Hate Crime Statistics, Law Enforcement Officers Killed and Assaulted, and National Incident-Based Reporting System. The NIBRS is a data collection which allows LEAs to collect information on each crime occurrence. The FBI designed NIBRS to generate data as a byproduct of federal, state, and local automated records management systems (RMS). The NIBRS collects data on each incident and arrest within 28 crime categories comprised of 71 specific crimes called Group A offenses. For each of the offenses coming to the attention of law enforcement, various facts about the crime are collected. In addition to the Group A offenses, arrest data only are reported for 13 Group B offense categories. When reporting data via the traditional Summary Reporting System (SRS), LEAs tally the occurrences of eight Part I crimes.

The most significant difference between NIBRS and the traditional SRS is the degree of detail in reporting. The NIBRS is capable of producing more detailed, accurate, and meaningful information because data are collected about when and where crime takes place, what form it takes, and the characteristics of its victims and perpetrators. Although most of the general concepts for collecting, scoring, and reporting UCR data in SRS apply in NIBRS (e.g., jurisdictional rules), there are some important differences between the two data collection systems. The SRS employs the Hierarchy Rule, i.e., in a multiple-offense incident, only the most serious offense is reported, and only eight Part I offenses can be reported. The many advantages NIBRS has over SRS include, but are not limited to, reports every offense occurring during the incident; revised, expanded, and new offense definitions; more specificity in reporting and using offense and arrest data for 28 Group A offense categories encompassing 71 crimes; distinguishes between attempted and completed Group A crimes; provides crimes against society; includes victim-to-offender data, circumstance, drug-related offenses, offenders suspected use of drugs, and expanded computer crime; and provides updated reports tied directly to the original incident. The Group A offense categories include animal cruelty; arson; assault offenses; bribery; burglary/breaking and entering; commerce violations;* counterfeiting/forgery; destruction/damage/vandalism of property; drug/narcotic offenses; embezzlement; espionage;* extortion/blackmail; fraud offenses; fugitive offenses;* gambling offenses; homicide offenses; human trafficking;

immigration violations;* kidnapping/abduction; larceny/theft offenses; motor vehicle theft; pornography/obscene material; prostitution offenses; robbery; sex offenses; stolen property offenses; treason;* and weapon law violations. The 13 Group B offense categories, for which only arrest data are collected, include bad checks; bond default;* curfew/loitering/vagrancy violations; disorderly conduct; driving under the influence; drunkenness; family offenses, nonviolent; federal resource violation;* liquor law violations; peeping tom; perjury;* trespass of real property; and all other offenses. (Offense categories followed by an asterisk (*) denote those reported by federal and tribal LEAs only.) Beginning in 2019, the NIBRS began collecting additional data values to capture information on domestic violence, cargo theft, and negligent manslaughter.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated number of LEAs submitting data to the UCR Program via NIBRS is 9,875. The FBI designed NIBRS to generate data as a byproduct of federal, state, and local automated RMS. Many LEAs have RMS capable of producing a myriad of statistics to meet their particular needs. LEAs forward only the data required by NIBRS to participate in the FBI UCR Program. Each month, it takes approximately two hours for an average respondent to respond, which is an annual burden of 24 hours. The two hours is the time required for a law enforcement agency's RMS to download the NIBRS data and send the information to the FBI.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with the NIBRS data collection is 237,000 hours (9,875 LEAs × 24 hours annually = 237,000 total annual hours).

If additional information is required, contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Melody Braswell,

Department Clearance Officer for the PRA, US Department of Justice.

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