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IN THIS ISSUE

CBO Estimates User Fee Reauthorization Would Require $740 Million

The Congressional Budget Office officially scored the Senate package to reauthorize the FDA's user fee agreements with the medical device and pharmaceutical industries, saying it would add $740 million to the agency's spending budget and a negligible amount to the country's deficit over its five-year life.

CBO estimated implementing the bill would increase user fee collections by about $1.7 billion in fiscal 2018, compared to the current generation of the agency's user fees.

The bill, S. 934, would have industry put up about $9 billion in total user fees before fiscal 2022 — about $1 billion from medical device companies under MDUFA, with the lion's share of $8 billion coming from the pharmaceutical industry through PDUFA, GDUFA and BsUFA — according to the CBO cost estimate.

The next iteration of MDUFA would require the FDA to set up electronic submission of 510(k) clearance and premarket approval bids,

(See **User Fee**, *Page 2)*

WHO to Develop Essential Diagnostics List

The World Health Organization is developing an Essential Diagnostics List to help countries create their own national lists of essential diagnostic tests and tools.

The WHO published its list of essential medicines on June 6, and the Expert Committee on the Selection of Essential Medicines recommended that the WHO develop an essential diagnostics list (EDL) as well.

The EDL will provide evidence-based guidance to countries to create their own national lists of essential diagnostic tests and tools, the organization said, noting that the list will "become an "important contribution to universal health coverage. "

(See **WHO**, *Page 6)*

New Zealand Updates Device Standards

New Zealand's Ministry of Health released new standards that will ensure all medical devices are properly named and identified for clinical and supply chain purposes in the country.

This extends the present standards for the New Zealand Medicines Terminology to the medical device domain. Namely, GS1 Global Trade Item Number (GTIN) is endorsed as the standard for device identification in the supply chain and for product traceability, while SNOMED CT is endorsed as the standard for device terminology in electronic health records and for clinical decision support.

The new standard, HISO 10024.2:2017, applies to medical device terminology and identification standards. The Health Information Standards Organization (HISO) supports and promotes the development and adoption of fit for purpose health information standards for the New Zealand health system.

The new standard covers all medical devices — from wound care products to wearables, to prostheses, to implantable devices and diagnostics — and ensures that medical devices can be safely tracked through the supply chain.

The country's single funder, Pharmac, manages expenditures for devices in public hospitals and is placing more emphasis on collective approaches to district health boards' supply chain activity. The standards will inform procurement and distribution decisions, because all devices will have a unique identification number and will replace proprietary and non-standard medical device coding methods.

At the same time, New Zealand is planning to introduce an electronic health record (EHR) system

(See **Standards***, Page 8)*

User Fee*, from Page 1*

change how the agency evaluates and approves those applications and tracks device safety.

CBO estimated that those provisions would require more than 200 additional full-time equivalent employees at an average total cost per FTE of $300,000 annually, totally $60 million a year, plus another $7 million for IT and other expenses. In all, the provisions would raise the FDA's costs by $243 million, including:

- $152 million to revise device inspection standards;
- $32 million to update agency procedures on receiving and evaluating clinical data;
- $20 million to increase communications with devicemakers on export certificates;
- $20 million for pilot programs on collecting and evaluating postmarket data;
- $11 million for a risk-based inspection schedule and to reauthorize accredited inspections; and
- $8 million for new regulations creating a path for over-the-counter hearing aids.

The fees paid by companies for the review of their products and facilities would offset most of the bill's increase in net discretionary spending, and direct spending would go up by $13 million under the proposed bill.

Meanwhile, revenues would be lowered by $2 million by fiscal 2022, while raising the total deficit by only about $15 million by fiscal 2027, the CBO estimated.

In addition to reauthorizing the user fee agreements, the bill also would require the FDA to implement some pricey changes to existing programs, reauthorize FDA and NIH grants, and require GAO reports to Congress not previously covered by user fees.

The CBO's estimate is based on the version approved by the Senate Health, Education, Labor and Pensions Committee in May, not on the proposed fiscal 2018 budget from the Trump administration, which calls for massive across-the-board hikes in user fees to make up for cuts in taxpayer-funded budget authority.
— Gayle S. Putrich

Pathways Can Shorten Devicemakers' Road to Approval

Devicemakers looking to speed their products through the development process can get help from three lesser-known FDA pathways, according to two experts.

Early feasibility studies (EFS), first-in-human studies (FIH) and the Expedited Access Pathway (EAP) program can substantially reduce the time spent in the clinical trial stage, said device consultants Caroline Rhim and Meaghan Bailey of NSF Health Sciences in an FDAnews-sponsored webinar in June.

Early feasibility studies are small clinical studies designed to gain early insights into an innovative technology during the development process before starting a larger clinical trial. First-in-human studies fall under the umbrella of EFS.

Early Feasibility

The EFS program allows for a circular approach where clinical data can be used to inform decisions regarding device and protocol changes as well as nonclinical testing, Rhim said. And in this case, more nonclinical testing may not always be necessary to go back to the clinical study, she said.

Rhim added that an EFS of a new device or a new intended use of an old marketed device includes use in a small number of subjects, generally fewer than 10. These studies may also be used to evaluate the device design concept and use an iterative process to facilitate both device and clinical protocol changes.

"The new approaches include the ability to make changes through, for example, five-day notices versus those requiring prior FDA approval, because the large majority of the changes will not affect how the results are interpreted, because they're not dependent on statistical analysis of patient-level data," said Rhim.

One of the major goals of this program, added Bailey, is to bring clinical trials to the United States first.

"It is not always appealing for a company to conduct early-stage clinical trials in the U.S. due to the stringency of IDE regulations as compared to regulations in some other non-U.S. countries," she said. "So this has been a pretty successful and efficient program that allows a company to have early, often, and consistent interaction with the agency, which is particularly beneficial for novel devices requiring clinical data."

These studies are given high priority within CDRH's review divisions, and can be a tremendous time and resource saver, Bailey noted. They save a company from doing unnecessary studies upfront and will inform appropriate studies that may need to be done in the future.

Expedited Access

The Expedited Access Pathway, Rhim said, is available for technologies that address an unmet medical need, and/or a life-threatening or irreversibly debilitating disease. This is a voluntary program that provides a manufacturer with priority review, increased interactive review, senior management involvement, and a case manager from the FDA.

"The thinking behind this is to have an open dialogue with the agency and foster an interactive process that will lead to either clearance, approval, or granting of these needed devices more quickly," Rhim said. "In this review paradigm, there may be more uncertainty that the agency is willing to accept, and you may be able to move some of the data requirements to the postmarket [stage]."

The final guidance for the EAP program was published in April of 2015. The 21st Century Cures Act signed last December, however, added a new "Breakthrough Devices" section to the Food, Drug and Cosmetic Act. While similar to the FDA's current guidance for EAP, breakthrough devices have some differences. For example, 510(k) devices are now eligible for the EAP program, and the Data Development Plan is

(See **Pathways***, Page 8)*

Australian Parliament Passes New Device Reforms

Both houses of the Australian Parliament passed new reforms contained in the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016.

The bill is the first in a tranche of three expected that will update the nation's drug and device regulations. The government said it would implement the reforms in a staged approach over the next two years.

Health Minister Greg Hunt told the Senate Standing Committee on Community Affairs that the bill would, "enable faster access to important new medicines and medical devices for Australian patients, as well as to streamline administration and reduce regulatory burden in several areas."

The bill allows for designated notified bodies within Australia to conduct conformity assessments for medical devices. These notified bodies will provide an alternative avenue, other than the TGA, to obtain a conformity assessment certificate. This move is expected to speed access to devices considerably, because devicemakers won't have to wait for notified bodies in Europe to conduct conformity assessments.

Under the new reforms, Australia will be able to use approvals from certain overseas regulatory agencies to satisfy its requirements for medical device approvals (*IDDM*, June 7).

The TGA will align its regulatory processes with the European Union wherever possible, particularly with respect to the classification of medical devices, essential requirements and adopting a risk-based approach. In addition, the TGA will establish target timeframes that reflect international benchmarks.

Expanded access to medical devices will also be available for devices under Category B, which could be subject to automatic approval in order to streamline the process for certain lower-risk devices under the Special Access and Authorized Prescriber Schemes. The TGA will develop an online system to enable better monitoring of those devices and to reduce administrative costs.

The bill also enhances patient safety by collecting more postmarketing safety data from sponsors to provide more information about new products approved under an expedited pathway.

Medical Technology Association of Australia CEO Ian Burgess said the association welcomed the passage of the new bill, particularly "the decision for greater use of overseas assessment to fast-track access to innovative and life-saving products."

MTAA member companies are mostly small-to-medium size companies that "complain about the avoidable red-tape, [and] this bill will go to streamlining the regulatory burden," Burgess said.

The Australian Dental Association (ADA) also praised the bill and the anticipated reduction in bureaucratic red tape.

"ADA has been a strong proponent for these reforms that will reduce the costs associated with conformity assessment," said ADA CEO Troy Williams.

483 Roundup: Four Devicemakers Cited for Inadequate Procedures

The FDA issued Form 483s to Jensen Industries, Tyson Bioresearch, OsteoSymbionics and Innovative Sterilization Techniques, citing problems with their procedures for corrective/preventive actions, complaints and MDRs.

Jensen Industries: Jensen Industries landed a Form 483 due to issues with corrective/preventive actions and quality system reviews.

The FDA issued the form following a March inspection of the firm's North Haven, Conn., facility. According to the agency, Jensen failed to follow its SOPs on corrective/preventive actions (CAPA). A CAPA initiated in July 2015, for example, failed to document the effectiveness of the action the company took in the specified time frame, while two CAPA actions opened in 2016 are still open past their due dates of February 2017, with no documentation justifying the continued openness.

Moreover, investigators found executive managers did not review Jensen's quality system, in contrast with the firm's SOPs, which require regular management reviews. In one case, the firm conceded one of the management reviews was not performed according to the established schedule. Jensen promised to correct both observations.

Tyson Bioresearch: The FDA hit Tyson Bioresearch on several of its procedures, including corrective actions, complaints, validation processes and written MDRs.

The agency issued a Form 483 after a March inspection of its Chun-Nan, Miaoli County, Taiwan, facility. According to investigators, the facility failed to initiate certain corrective and preventive actions in 2015 and 2016, contravening its own quality objectives.

The facility also did not validate a process used in the manufacturing of its glucose test strips according to its established procedures, and has yet to establish several procedures that describe the process controls necessary to ensure adherence to specifications.

Further, investigators found complaints from 2016 and 2017 for Tyson's Blood Glucose Monitoring System that, contrary to the company's SOP, did not contain documented evidence of MDR evaluation. The FDA also faulted Tyson's written MDR procedures, noting its MDR procedures are simply a copy of the U.S. FDA MDR regulation.

OsteoSymbionics: The FDA issued a Form 483 to OsteoSymbionics for numerous procedural problems with corrective/preventive activities, nonconforming materials and equipment calibration.

OsteoSymbionics landed the form shortly after a March inspection of its Cleveland facility. According to FDA investigators, the firm has not yet completed a corrective/preventive action opened in June 2015, and there is no documented evidence the CAPA in question, which involved updating milling procedures, took place.

The facility's nonconforming material reports (NCMRs) are also incomplete and do not meet the company's NCMR procedures' requirements. A review of 14 NCMRs found 10 did not document the decision not to investigate and three failed to fill out the investigation and approval sections.

Investigators also found information missing in the facility's supplier files, including lack of supplier evaluation records, outdated ISO certification files and missing ISO certificates.

Lastly, the facility's Heat Sealer equipment, used for sterile packaging of cranial implants, was calibrated for time and temperature but not for pressure. OsteoSymbionics promised to correct all observations.

Innovative Sterilization Technologies: Innovative Sterilization Technologies landed an FDA Form 483 that cites inadequate corrective/

(See **483s***, Page 6)*

WHO, *from Page 1*

Essential drug lists have helped increase access to needed medicines at more affordable prices in developing nations, and WHO expects that the essential diagnostics list will provide the same benefit for needed diagnostic tests.

"It's clear that treatment of an illness will not be effective if it is not diagnosed correctly," said Suzanne Hill, WHO director of Essential Medicines and Health Products. "The EDL will be another useful tool to help countries address their disease burden by focusing on evidence-based diagnostic tools."

By diagnosing disease earlier, the burden of disease can be reduced significantly in many low-income nations. Diagnostics can also identify subpopulations for which certain medicines may be more effective, and toxicity can also be monitored via these diagnostics.

WHO said that early diagnosis has important implications for prognosis for patients, and the committee, "recognized that Member States and countries might seek advice about which technologies to prioritize, how to shift from one technology to another, and which technologies should accompany essential medicines since they are strongly interconnected."

The EDL list will likely focus on in vitro diagnostics (IVDs) for TB, malaria, HIV and hepatitis B & C first, and then it will expand the list to other disease areas, particularly antimicrobials and non-communicable diseases.

WHO said that TB is one of the top 10 causes of death worldwide. In 2015, 10.4 million people contracted TB, and 1.8 million died from the disease; more than 95 percent of TB deaths occur in low- to middle-income countries.

To lay the groundwork for the EDL, WHO is creating an expert advisory group called SAGE IVD, which will advise the organization on global policies and developing the EDL.

Some of the benefits expected from the EDL are improved patient care, greater capacity to diagnose diseases during outbreaks, increased affordability of tests, improved regulation and quality of diagnostic tests, and strengthened capabilities of national laboratories.

The committee recommended that WHO use the list of essential medicines as a model for developing the EDL process, methodology and transparency.

It also recommended that strong links be maintained between the SAGE-IVD committee and the Expert Committee on Selection and Use of Essential Medicines. It suggested that the EDL "be instrumental in developing medical guidelines as well as laboratory-accreditation schemes."

483s, *from Page 5*

preventive action (CAPA) procedures, complaint handling, MDR procedures and incoming product acceptance.

The agency issued the form after a March/April inspection of the company's Dayton, Ohio, facility. Inspectors noted that the company's CAPA procedures do not clearly define the meaning of "unfavorable trend," nor have its evaluations of CAPAs ensured the actions were effective and did not adversely affect the finished device.

The facility's complaints procedure, meanwhile, does not define how to document complaint investigations or closures of warranty complaints for products that were not returned for assessment. Since last July, the company has "voided" nearly 50 warranty complaints because no product was returned.

The agency also found the acceptance test performed on Innovative Sterilization's tamper locks is not clearly defined and references a standard operating procedure that is still in draft form. Similarly, its written MDR procedure has no standardized review process or a method of evaluating when a complaint should be reported as an MDR.

The 483s can be read here: www.fdanews.com/06-21-17-roundup483s.pdf. — Zack Budryk

APPROVALS

Eko Devices' Home Heart Monitor Scores FDA Approval

The FDA has approved a Berkeley, Calif., tech company's home heart monitoring device.

The agency signed off on the product, manufactured by Eko Devices, earlier this month. The handheld device combines elements of a stethoscope and electrocardiogram and links to a smartphone app that transmits heart activity to the owner's doctor for remote monitoring.

The device's user-friendly design, developed by the manufacturers of one of the first "smart stethoscopes," aims to reduce heart failure and atrial fibrillation.

FDA Signs Off on Medtronic's Heart-Valve Replacement Protector

A cerebral protection system aimed at protecting heart surgery patients from strokes scored FDA approval earlier this month.

The agency approved Medtronic's Claret Sentinel Cerebral Protection System, which captures stray particles that break loose from aortic valves during transcatheter aortic valve procedures. If the particles aren't contained, they can travel to the brain and cause strokes or other adverse events.

However, Sentinel did not demonstrate a statistically significant decrease in blockage formation in specific areas of the brain during the trial process, meaning insurers may not reimburse the cost of the device once it hits the market.

FDA Approves Titanium 3D-Printed SI Joint Implant

The FDA granted approval to SI-BONE's titanium 3D-printed implant for the sacroiliac joint (SI).

The San Jose, Calif.-based devicemaker also developed the iFuse Implant System, a minimally invasive surgical device used to treat SI joint disorders. The implant's structure encourages bone growth and mimics the trabecular structure of cancellous bone, according to SI-BONE.

The implant was formally granted a patent on May 30 and both the implant and its structural design will retain in their patents through September 2035. The manufacturers are optimistic the approval represents increased integration of 3D printing technology into the implant device sector.

BRIEFS

India Changes Acceptance Criteria for IVD Test Kits

India's Ministry of Health and Family Welfare has revised the acceptance criteria for in vitro diagnostic devices to detect HIV, HBsAg and HCV.

The change was recommended by the Technical Committee following quality control and lot release testing. The June 13 order recommends the following criteria for acceptance of sensitivity and specificity for test kits: anti HIV ½ and or HIV-1 p24Ag must test sensitivity at 100 percent and specificity at 98 percent or greater; the HBsAg test must test sensitivity at 100 percent and 98 percent or greater for specificity; and the Anti-HCV test must test sensitivity at 100 percent and specificity at 98 percent or greater. The rapid test kit should test sensitivity at 99 percent.

South Africa Calls for Nominations For New Regulatory Authority

The South African Health Products Regulatory Authority is asking the public to submit nominations for the board of the new authority.

SAHPRA positions to be filled include up to 10 people with expertise in the field of medicine, medical devices, in vitro diagnostics, clinical trials, good manufacturing practices, public health and epidemiology. The agency is also looking for additional staff who have knowledge of the law, good governance, finances, information technology and human resource management.

Employees of national, provincial and local government agencies are not entitled to additional remuneration if they serve on the SAHPRA board. Nomination forms may be obtained from the Department of Health website at http://www.doh.gov.za/.

Pathways, *from Page 3*

now an optional part of the EAP program, where previously, it was required for acceptance.

"Up until recently, only Class III—or essentially PMA- and de novo-eligible devices—were considered for EAP designation," said Rhim. "Under the Cures Act, Class II devices have been added for consideration, which will expand the number and types of devices to be eligible for EAP designation."

One caveat, she added, involves combination products. If your device component qualified for the EAP program, you should talk to the FDA early to see if the EAP pathway is feasible, because combination products have other unique considerations that may preclude them from having this expedited access review. With these changes, there are many moving pieces that you will need to consider, said Rhim.

"So if the EAP is something you might be interested in, keeping an open dialogue with FDA on this option will be critical given all of the changes with 21st Century Cures," added Bailey.

Guidance Coming Soon

Since the agency will be issuing a revised draft EAP guidance by the end of this year, companies may want to wait a bit longer before leaping into this pathway, said Rhim.

"Since the guidance is currently being modified and not yet issued, there could be substantial changes," said Bailey. "This is not to say you should not consider this pathway, but since the details of the program and its parameters are shifting, it can add uncertainty to a regulatory pathway."

Depending on the specifics of your device and circumstances, however, it may be the case that the new guidance could increase the likelihood of being accepted into this program. So it could benefit you to wait for that guidance to be published, Bailey said.

"Establishing your regulatory strategy is a journey, but the foundational steps of determining your indications for use and researching the competitive market should never be skipped," said Bailey. "In many cases, FDA may have premarket regulatory pathways that can help you get to market more quickly, but you have to keep up with changes to old programs as well as keep your eye out for the addition of new ones.

She added, "FDA is open to interactive dialogue. You just have to ask."

Standards, *from Page 2*

that will document medical devices prescribed, as well as patient allergies, adverse reactions and other medical conditions. When patients are prescribed medical devices, they will be immediately scanned into the SNOMED CT system, which becomes part of the patient's electronic health record.

The GS1 standards will align New Zealand with international markets by using the GTIN device identifier for UDI codes. The move allows for information to cascade down to clinical coding and decisionmaking, government funding, regulatory and safety information with Medsafe, as well as data from suppliers to initiate recalls more effectively.

Next steps include:

- A new medical device terminology system built on SYNOMED CT. The new devices portion of the Pharmaceutical Schedule will be translated into this format for funding and procurement decisions;
- The scope of the New Zealand Universal List of Medicines will be extended to include medical devices and will bridge the clinical and supply sides by linking each container with GTIN codes;
- Transaction data will include a combined set of data elements and unique device identifiers, including the SYNOMED CT, GTIN, batch number, expiration date and product serial number; and
- Product labels will be required to include machine-readable UDIs based on GTINs.

Read the notice here: www.fdanews.com/06-20-17-NewZealand.pdf.

Cardiac Devices Pose Cybersecurity Challenges, Study Finds

A new study of the four biggest makers of pacemaker systems found thousands of software vulnerabilities, highlighting an industry-wide problem with software security updates.

The study, undertaken by cybersecurity firm WhiteScope, looked at pacemakers, implantable cardioverter defibrillators, pulse generators, and cardiac rhythm management devices, and found potential weak spots common to the devices — including unencrypted firmware, hardcoded credentials and radio-frequency activation. That's in addition to vulnerabilities found in third-party software libraries.

Programmers from all four pacemaker manufacturers were "struggling with updates, and every vendor had thousands of outdated libraries," said Billy Rios, founder of WhiteScope, and co-author of studies on medical device security that have been adopted into DHS literature and FDA pre- and post-market guidance.

Rios said he worries that a certain amount of risk with implantable devices is inevitable. The devices "go inside someone's body and they have to last for decades," he said. They have multiple components that all have to work together using custom radio communications and custom network communications, and the foundational technology behind the device is very complicated.

"The more complex a system is, the more vulnerable it is by nature," said Rios.

According to Rios, what's needed is for the various parts of the device ecosystem — including manufacturers, regulators and doctors — to take their own deep look into cybersecurity vulnerability so they can come up with ways for securing systems.

Read the WhiteScope study here: www.fdanews.com/06-08-17-Whitescope.pdf.
— Suz Redfearn

Senate Healthcare Bill Would Repeal Medical Device Excise Tax

Senate Republicans Thursday unveiled their hotly anticipated version of a bill to replace the Affordable Care Act, which includes the repeal of a much-maligned medical device excise tax.

The medical device tax, a 2.3 percent levy on U.S. sales of prescribed medical devices, went into effect in 2013 but is currently on a two-year moratorium that began in January 2015. If changes are not made—via a repeal-and-replace move on ACA or another bill, as with the current but temporary relief—it is set to be reinstated in 2018.

Estimated to bring in about $20 billion over 10 years, the tax is intended to ensure that the medical device industry contributes to the cost of healthcare reform provisions under ACA while benefiting from higher sales under the law's improved health coverage.

The House bill, which died on the floor in March but was later revived and passed, included the same provision.

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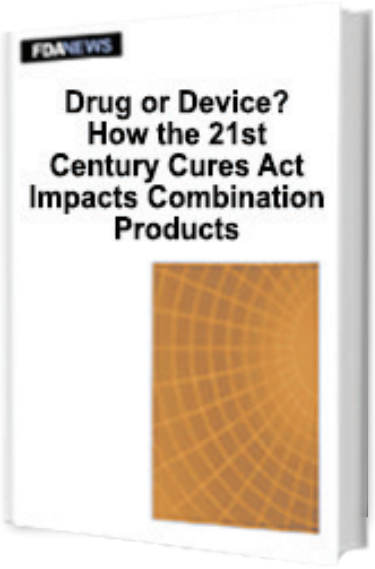

Drug or Device? How the 21st Century Cures Act Impacts Combination Products

Combination products remain one of the most difficult regulatory challenges for life sciences innovators.

Which FDA Center has the lead?

Will I need one marketing application or two?

Will I need a drug to be cross-labeled and approved for use with my device?

These and many more questions can make combination product sponsors feel like they are entering an unforgiving regulatory labyrinth.

The 21st Century Cures Act requires the FDA — over the next several years — to issue guidance that will create a structured process and best practices for managing the development and reviews of drug/device/biologic combinations. The law provides for a streamlined approach to GMP for combination products similar to what the agency has recently announced through rule and guidance.

Drug or Device? How the 21st Century Cures Act Impacts Combination Products takes a close look at the FDA's new authority governing combination products, as well as several new provisions under the 21st Century Cures Act that could usher in a new era of interdisciplinary product reviews at the FDA. You will learn:

- How the 21st Century Cures Act defines primary mode of action
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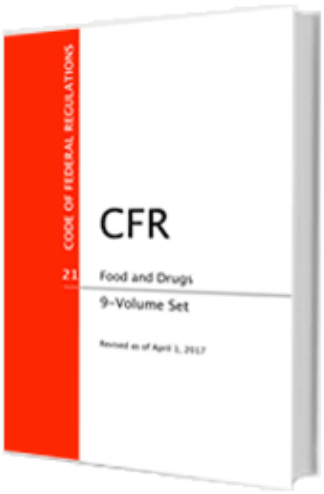

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